COMPARISON BETWEEN FENTANYL AND DEXMEDETOMIDINE FOR AWAKE FIBEROPTIC INTUBATION

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CHENNAI

CERTIFICATE

This is to certify that the dissertation titled **"COMPARISON BETWEEN FENTANYL AND DEXMEDETOMIDINE FOR AWAKE FIBEROPTIC INTUBATION"** is a Bonafide original work done by **DR. S. MAHAMINU** during May 2016 - May 2019 in partial fulfilment of the requirements for **M.D. (Anaesthesiology) Branch X**- Examination of the Tamilnadu Dr.M.G.R. Medical University to be held in May 2019.

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DECLARATION

I **Dr. S. Mahaminu** solemnly declare that this dissertation, titled **"Comparison Between Fentanyl and Dexmedetomidine for Awake Fiberoptic Intubation"** is a Bonafide record of work done by me in the Department of Anaesthesiology, Govt. Theni Medical College and Hospital, Theni under the guidance of **Prof. Dr. M. Balasubramani, M.D., D.A.,** Associate Professor of Anaesthesiology, Govt. Theni Medical College & Hospital, Theni.

This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai in partial fulfilment of the University regulations for the award of degree of M.D. (Anaesthesiology), Branch X - examination to be held in MAY-2019.

Place: Theni

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CONTENTS

INTRODUCTION

Ever since the dwan of modern medical core Surgical practice, the tracheal intubation techniques in Anaesthetic care has rapidly evolved and still evolving into newer modalities. The importance of tracheal intubation in securing airway is obvious and needs no emphasis.

The evolution of tracheal intubation, though there are evidences as early as 1500 BC in Egyptians & Hindu scripts, can be roughly traced from 19th century onwards. In early 1870's, Trendelenberg from Germany performed the first endotracheal Anaesthesia in Man. McEwen in 1878 successfully performed the first elective endotracheal intubation for anaesthesia (1). Tracheostomy and Intubation were widely used in the first world war. The invention of First Anaesthetic Laryngoscope in 1913 by Jackson and further modification by Magill, Miller and Macintosh accelerated the script from Invasive Tracheotomy/Tracheostomy intubation to Non Invasive Non-Surgical orotracheal route.

Not every airway lends itself easier for orotracheal intubation. A certain group of patients present with difficult airway in both emergency and elective settings that a conventional orotracheal intubation using Laryngoscope is difficult to perform. Further, there is an additional risk

of loss of Muscle tone and consequent Airway obstruction when General Anaesthesia is induced in these patients.

A breakthrough technique for successful intubation in the above described group of patients with difficult airway is the Awake Fiberoptic Intubation (AFOI) which has been in practice since 1960's and gaining wider popularity in the management of Difficult Airways. Nowadays, the Fiberoptic intubation has become the instrument of first choice in difficult intubation cases particularly after the publication of the American society of Anaesthesiologists (ASA) guidelines in Difficult Airway Management(2). Further Awake Fiberoptic Intubation is safe with a higher success rate due to the following reasons.

i. Preserved Muscle tone avoids airway collapse and keeps the airway patent.
ii. Spontaneous breathing on command can open the obstructed airway passages.
iii. Chances of desaturation is minimal in awake state/spontaneous breathing (3).

Endotracheal Intubation using a Fiberoptic bronchoscope in the Awake State, if performed without proper sedation, can be an extremely unpleasant and discomforting experience for the patient. At present,

various classes of drugs are used for providing sedation during Awake Fiberoptic Intubation. They are,

i. Benzodiazepine(Midazolam)
ii. Propofol
iii. Alpha$_2$argonists (clonidine &Dexmedetomidine)
iv. Opioids (Fentanyl and Remifentanyl)
v. Ketamine.

The above mentioned drugs are either used alone or in combination with others. An Ideal sedative for the AFOI should provide,

i. Patient comfort
ii. Anxiolysis
iii. Amnesia
iv. Patent airway with stable Hemodynamic
v. Attenuated airway reflexes / Antitussive properties.

The search for the Ideal sedative drug or a combination of them and their dosage for sedation during AFOI still continue.

This study aims to test the efficacy and efficiency of Dexmedetomidine and Fentanyl on various parameters for sedation during Awake Fiberoptic Intubation.

OBJECTIVES OF THE STUDY

1. To study, obtain results and compare the efficiency and efficacy of Dexmedetomidine (1ug/kg) and Fentanyl (2ug/kg) for sedation during Awake Fiberoptic intubation.
2. To study the patient's comfort and compliance for intubation in terms of COUGH SCORE and POST INTUBATION SCORE for both drugs.
3. To study the depth and quality of sedation in terms of RAMSEY SEDATION SCORE for both drugs.
4. To study the events of desaturation throughout the procedure using SpO_2 (Peripheral Capillary Oxygen saturation) for both drugs.
5. To study the changes in Baseline Heart Rate and the Post intubation Heart Rate for both drugs.
6. To study the changes in Baseline Mean Arterial pressure and the Post intubation Mean Arterial Pressure for both drugs.
7. To look for any side effects of both drugs.

REVIEW OF LITERATURE

AWAKE FIBEROPTIC INTUBATION

INDICATIONS:

1. anticipated difficult airway or difficult intubation,

- Previous history of difficult intubation
- Suspected difficult airway from patients history and physical examination
- Presence of abnormalities like temporo mandibular joint ankylosis, obesity, micrognathia.

2. Prevention of aspiration in high risk patients.

3. Avoidance of cervical spine movement in patients with suspected cervical spine injury.

4. Therapeautic and diagnostic applications

- Clearing of airway secretions
- Unexplained high airway pressure and hypoxemic conditions
- Observation of vocal cord paralysis, tracheomalacia, airway stenosis
- Correct positioning of endotracheal tubes
- Endotracheal tube exchange

- Use in supraglottic airway devices, retrograde intubation.

5. Prevention of traumatic effects of oral or nasal intubation (loose tooth, nasal polyps, dental prosthesis).

6. Routine intubation.

CONTRINDICATIONS FOR AFOI

1. Uncooperative patient
2. Untrained anaesthetist or endoscopist
3. Equipment failure
4. Severe upper airway obstruction like foreign body - may be used for diagnostic purposes
5. Massive trauma leading to disruption of upper airway
6. Perilaryngeal abcess / mass, vocal cord damage are moderate/ relative contraindications.

EQUIPMENTS

1. FIBEROPTIC BRONCHOSCOPE

The components of a fiberoptic bronchoscope include,

a. Eyepiece
b. Control section comprising

   Angulation lever

Suction port

Working channel port

c. Insertion cord

d. Universal cord

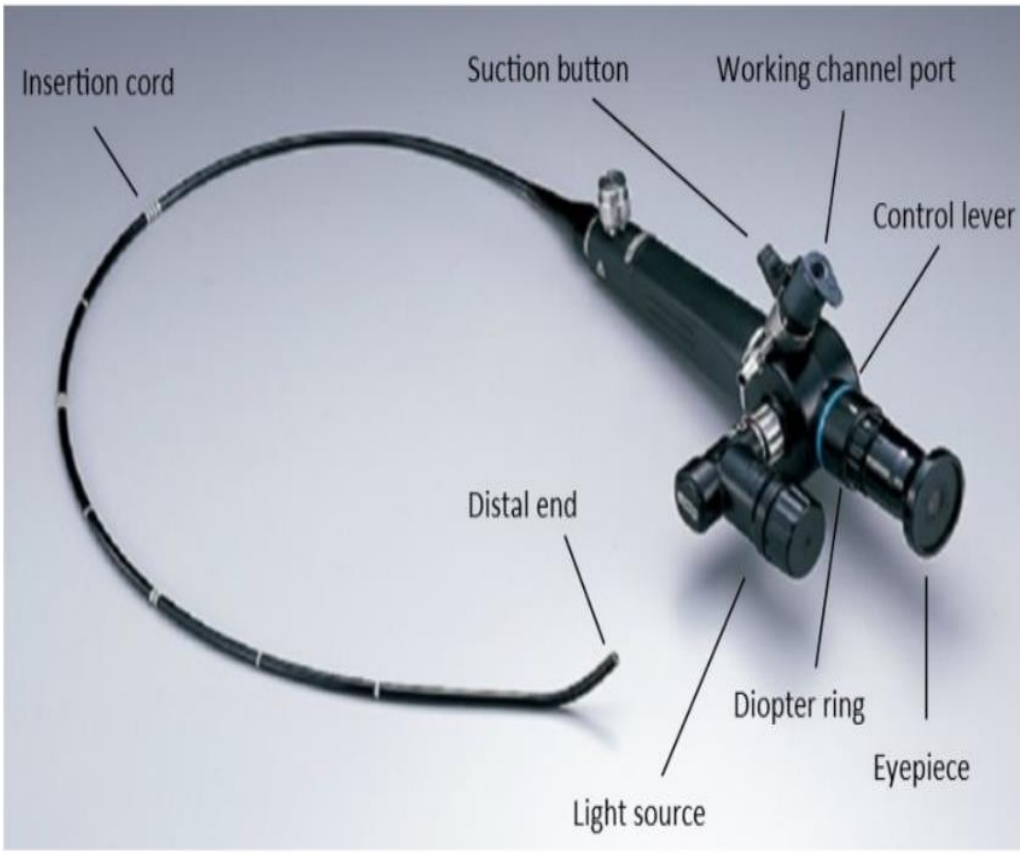


Figure showing parts of fiberoptic bronchoscope

The eyepiece comprises of lens and a focusing ring which can be adjusted to sharpen the image to the operator. A video camera can be attached to it.

The control section which is the working handle of the bronchoscope.

The angulation lever flexes or deflexes the distal tip of the bronchoscope. The rotational movement of bronchoscope with flexion/deflextion of distal tip help it to achieve the 360˚ panoramic view.

The suction port valve when pressed clears secretion.

The working channel port provides for injection of drugs/ fluids.eg- local anaesthetic drugs can be instilled in the spray as we go technique.

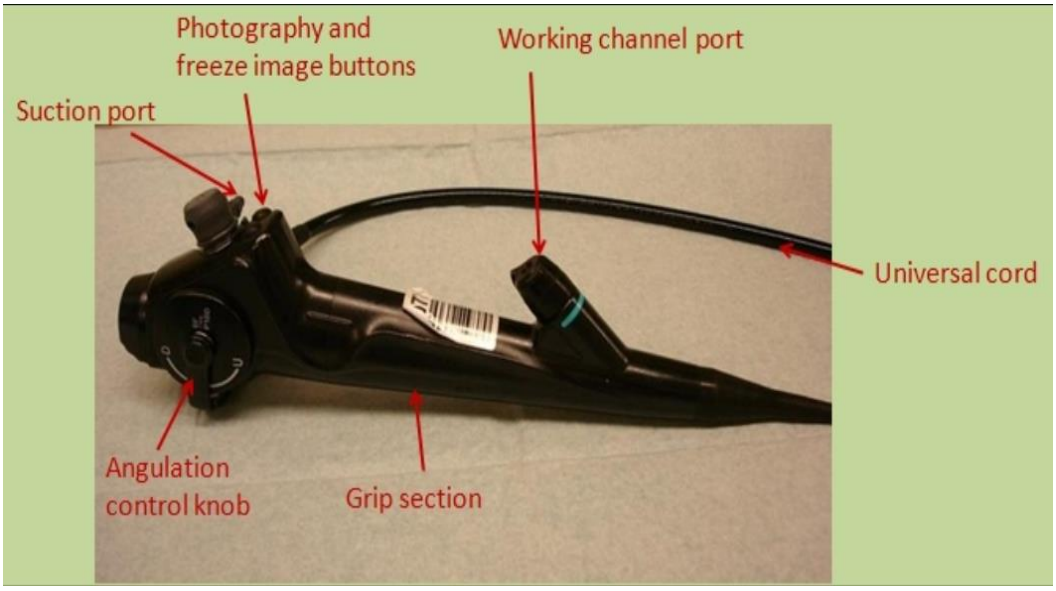


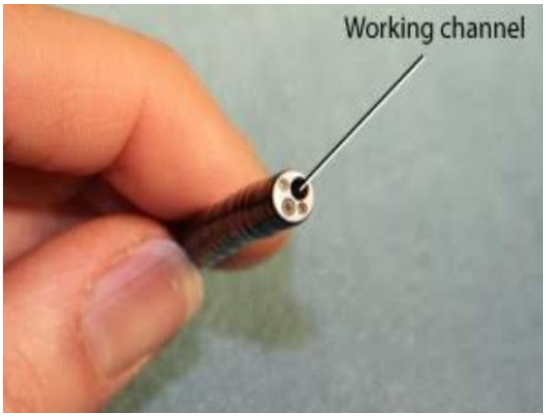
Figure showing the parts of working channels of fiberoptic bronchoscope

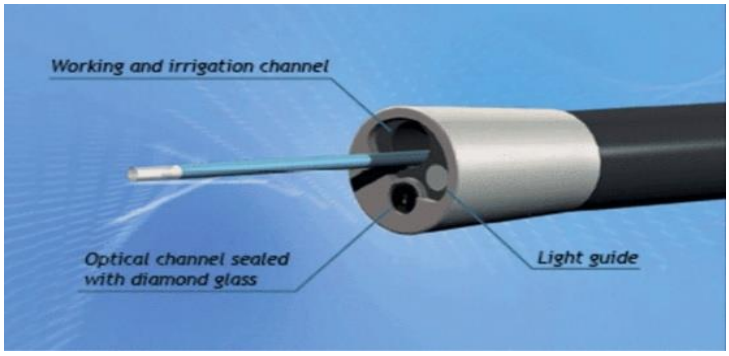
The insertion cord comprises of light guide bundle, fibroptic bundle, angulation wires and the working channel encased in a smooth plastic shell and running from the handle to the tip of the fiberoptic bronchoscope.

The light guide bundle consists of 25,000-30,000 non coherent glass fibres which are around 25-30 micron meter in diameter and they transmit the light towards tip.

There are two angulation wires controlled by angulation lever in the control section which helps in flexing/deflexing the distal tip of Fiberoptic bronchoscope. Up and down movement of angulation lever allows tip of FOB to move in opposite direction by 240◦-350◦.

The working channel running from the handle to the tip of fiberoptic bronchoscope has a diameter of about 1.2-2.8 mm. The tip of bronchoscope has an objective lens-2mm in diameter with a fixed focal and short field of view (75◦-120˚).

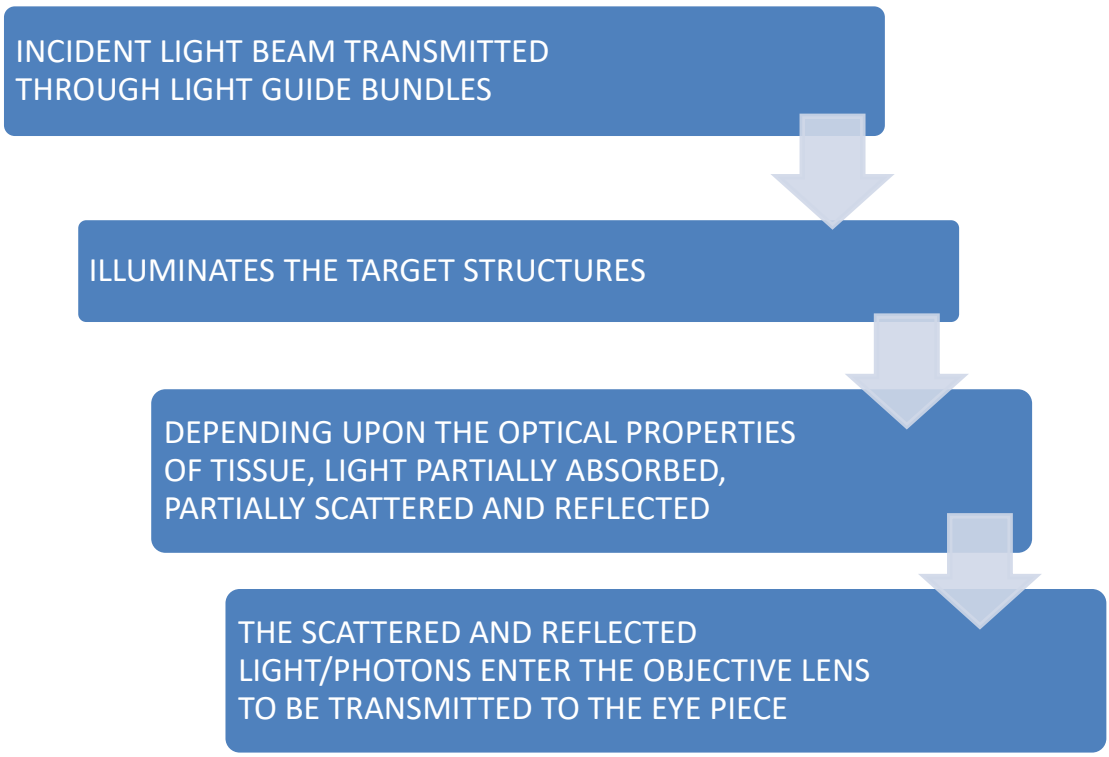




The universal cord helps in transmitting light from the light source to fiberoptic bronchoscope

Figure showing universal cord connecting light source to fiberoptic bronchoscope.

PRINCIPLE OF FIBEROPTIC BRONCHOSCOPE



The quality of image depends on,

a. Objective and eyepiece lens
b. Intensity of light
c. Density and number of glass fibres in the light guide and fiberoptic bundles

The fiberoptic bronchoscope cart forms a vital part of difficult airway management and should be kept always ready. The cart should ideally have,

a. clean fiberoptic bronchoscope

b. light source

c. video monitor

d. bronchoscope swivel adapters

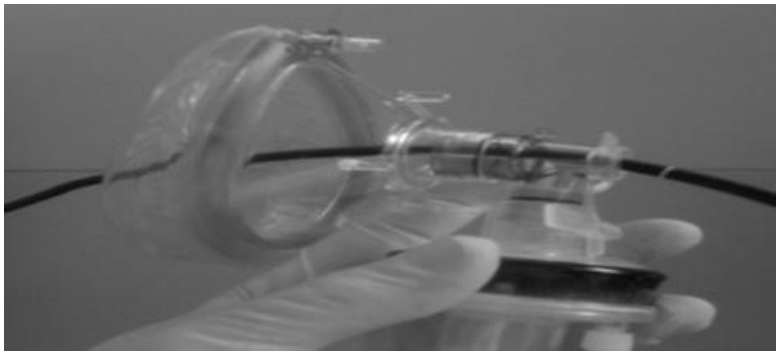
e. endoscopy masks

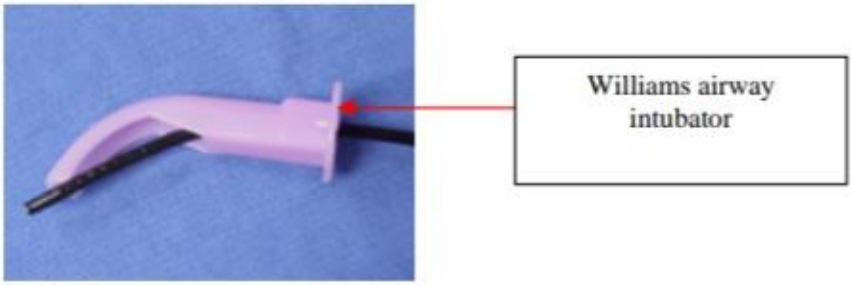
f. oral airway/nasopharyngeal airway

g. cotton tipped swabs, gauzes, atomizers

h. local anaesthetics (2% and 4% lignocaine)

I. suction catheters





Figures showing bronchoscope inserted through swivel connector in facemask and endoscopy mask respectively.

ENDOTRACHEAL TUBES:

The ETT is a device that is inserted into the trachea to deliver gases and vapour to and from lungs (4). The ETT have been most vital part in securing airway since advent of general anaesthesia.

Parts of ETT

ETT comprises of

1. PATIENT END/DISTAL END

2. MACHINE END/PROXIMAL END

The distal end of ETT can be labelled as,

Bevel

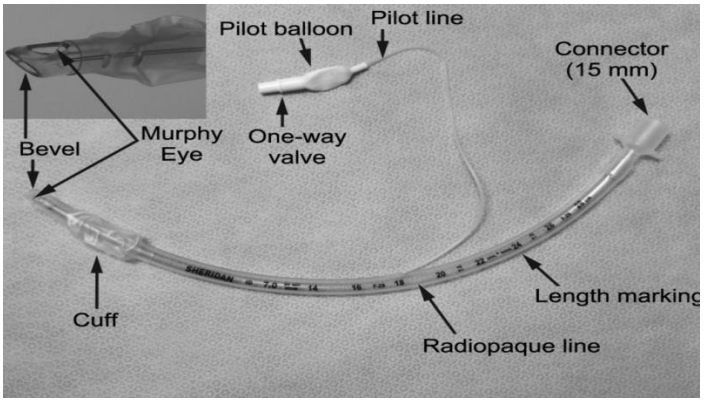
Murphy eye

Curve of the tube

Tracheal tube material

Markings on the tube

Tube cuff



The distal end is inserted into the trachea. There is a slanted portion at the distal tip called bevel facing left when tube is held in anatomical position to facilitate the insertion from right and for better visualisation of laryngeal structures. Bevel provides for easy insertion in between vocal cords and avoiding their injury.

Opposite to the bevel there is a hole called murphys eye. An important advantage of murphys eye is that it provides for an alternate port for gas movement in and out of the tube in case the bevel gets blocked.

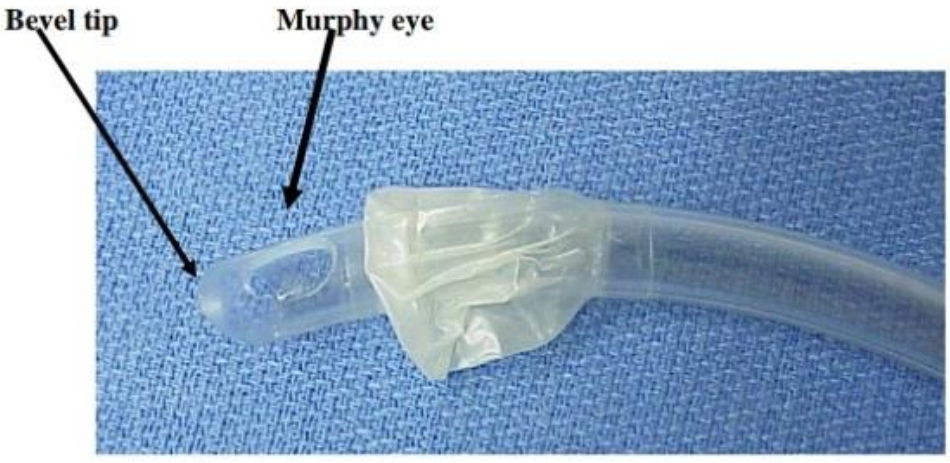


Figure showing the distal end of ETT

The ETT have a preformed curve matching the anatomical curve of the airway. It resembles an arc of a circle with radius of curvature of 140±20 mm.

The markings on the tube include,

1. A longitudinal line running throughout the length of tube which is radio opaque for indicating the correct placement in x ray.
2. A transverse black line just above cuff helps in ideal insertion of correct length of the tube so that the black line is visible just above the larynx. This ensures that tube is neither too in nor too out of larynx.
3. Marking describing oral or nasal route of intubation, tracheal tube size, name of manufacturer.

ETT is mainly made of red rubber/natural latex or PVC. The red rubber/ latex tubes can be reused after sterilisation but may be allergic and irritant. The PVC ETT are non irritant, disposable, transparent and in expensive and most commonly used.

Ideal tube size in average adult male is 8.5 mm ID and for adult female is 7.5mm

An inflatable sleeve near the patient end is called cuff. An inflated cuff seals the space between tube and tracheal wall. The cuff is inflated

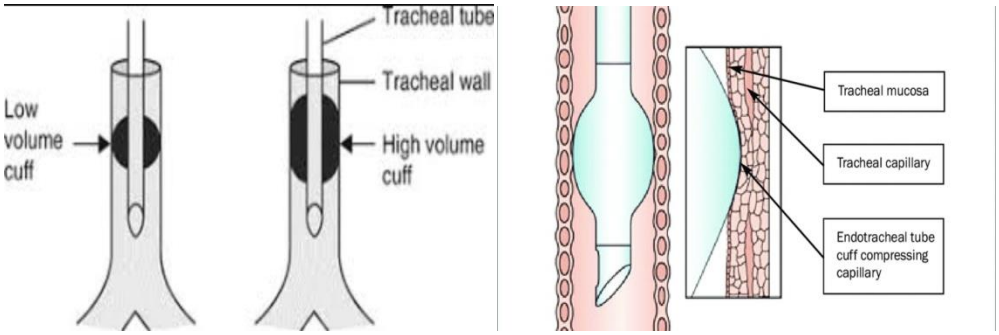
by an inflation tube with pilot balloon which has a one way inflation valve .There are two types of cuff,

1. Low volume, high pressure cuff
2. High volume, low pressure cuff

The low volume high pressure cuff are made of thick rubber with low compliance and require a higher pressure to inflate with a relatively lower volume. They inflate in a circular fashion rather than conforming to shape of trachea. They provide better protection against aspiration and better visibility during intubation. However the higher pressure can be transmitted to the tracheal wall thereby reducing the tracheal wall mucosal pressure to critical levels leading to mucosal ischemia, scarring and tracheal stenosis in case of prolonged use.

The high volume, low pressure cuff are made of thin inelastic PVC material and has a higher compliance. This type of cuff conforms to shape of trachea with large area of contact along the wall and exerts little pressure on the tracheal wall mucosa and thus can be used for prolong periods. Pressure within cuff can therefore be kept much lower and can achieve a seal with minimal risk of mucosal blood flow occlusion.(5) .However these types of cuff may be more difficult to insert as the larger area of contact obscures view of tube tip. Many microfolds persist in cuff creating small channel even after a good seal is achieved resulting in

entry of pharyngeal contents into the trachea resulting in ventilator associated pneumonia.



The recommended pressure on lateral wall of trachea is 18-25 mm Hg in normal adults.

The PROXIMAL END of ETT projects from the patient and receives the connector. It has a 15mm male fitting. The size of connector and ETT should be same in ID. The straight and 90˚ curved connectors are commonly used (6). The proximal end of connector is attached to catheter mounts which are made up of a metal tube or plastic tube which are connected to the breathing circuit.

AWAKE FIBEROPTIC INTUBATION- PROCEDURE

The awake fiberoptic intubation technique is usually performed in presence of a difficult airway or anticipated difficult airway. Thus assessment of airway becomes the first vital part in any mode of intubation. The two widely used airway assessment techniques are,

a. 1-2-3 rule

b. Modified mallampatti classification

1-2-3 rule is

1. Ability to insinuate tip of 1 finger into temporomandibular joint space during opening and closing of mouth in front of tragus.
2. Atleast 2 finger breadth between upper and lower incisors indicating adequate space between jaws for introduction of laryngoscope blade and ETT.
3. A Thyromental distance of more than three finger breadth measured between thyroid notch and symphysis menti.

MODIFIED MALLAMPATI CLASSIFICATION

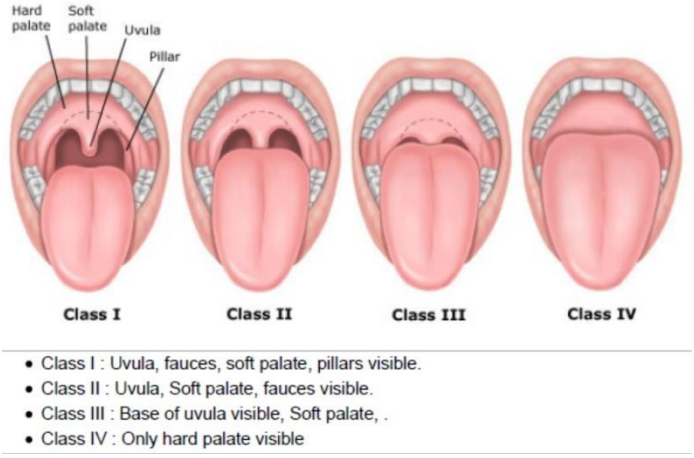


Figure showing Modified Mallampati Classification

Once the decision to undertake awake fiberoptic intubation is taken, the following steps are mandatory.

a. Psychological preparation

b. General preparation

c. Pharmacological preparation

d. Intubation using fiberoptic bronchoscope

PSYCHOLOGICAL PREPARATION:

Winning the patients confidence and cooperation is particularly important when endo tracheal intubation is planned in awake state (7). The preanaesthetic time is ideal for psychological preparation. Anaesthesiologist must explain to the patient using less medical terms. Further a written informed consent detailing the whole procedure should be obtained.

GENERAL PREPARATION:

Intravenous access is secured using an 18 gauge IV cannula. Monitors are connected to record the baseline heart rate, blood pressure, pulse oximetry, electrocardiography. A difficult airway cart, oxygen delivery system, suction apparatus, emergency drug tray, drugs like local anaesthetics, vasoconstrictors should be kept ready.

PHARMACOLOGICAL PREPARATION:

Pharmacological preparation involves administration of Antisialogogues

Topicalization of airway

Sedatives

Vasoconstrictors- if nasal route is chosen

ANTISIALOGOUGES

AFOI requires a clearly visualised airway without secretions. Further they prevent dilution of local anaesthetics, washing of topical agents down the esophagus and formation of secretion barrier between local anaesthetics and airway mucosa. Glycopyrrolate at a dose of 4 µg/kg is commonly used.

LOCAL ANAESHESIA OF THE AIRWAY

Anaesthesia of airway can be achieved by

Topical lignocaine

Nerve blocks

TOPICAL LIGNOCAINE:

Upper airway:

Using a lidocaine spray 10%- the palate, valleculae, tonsillar pillars, epiglottis and upper larynx can be anaesthetised.

Figure showing 10% lignocaine spray

Lower airway:

In recent days topical anaesthesia is achieved using,

Aerosol method,

Spray as you go technique using fiberoptic bronchoscope during intubation procedure.

AEROSOL METHOD-

Involves the administration of a nebulised lidocaine (4ml 4%) by facemask

Has an advantage of topicalizing airway without needling.

Figure showing nebulization of lower airway by aerosol method

SPRAY AS YOU GO TECHNIQUE:

The spray as you go technique is often used as a supplementary local anaesthesia technique when the patient has partial or nil pharyngeal or transtracheal anaesthesia.

In this method a quick pulse of 1 ml 2-4% lidocaine is injected through the working channel of fiberoptic bronchoscope, when the tip of the bronchoscope reaches areas with insufficient anaesthesia.

The suction procedure has to be avoided during this technique so that the local anaesthetic is not lost.

Another method is to pass an epidural catheter through the working channel of FOB and extend the catheter tip 1 cm beyond FOB tip. A syringe is now attached and LA is injected. The spray goes further distance away preventing obscuration of view.

Figure showing epidural catheter inserted in bronchoscope for spray as you go technique

NERVE BLOCKS:

The commonly used nerve block for airway anaesthetisation are Glossopharyngeal nerve block

- Transtracheal block
- Superior laryngeal nerve block

The nerve blocks are generally used in a patient who is not cooperative or with limited mouth opening or as a rescue method when hemodynamics changes and cough due to topical application of local anaesthetics are undesirable.

The glossopharyngeal nerve cranial nerve (IX) , Supplies sensory innervations of soft palate, the posterior third of the tongue, tonsils and the pharyngeal mucosa and occasionally the lingual surface of the epiglottis(8), which are all the afferent components of gag reflex. The glossopharyngeal nerve is bilaterally blocked by injecting 2ml lidocaine at the base of each anterior tonsillar pillar. Alternatively a pledget soaked in local anaesthetic is to be kept in piriform fossa each side for 5-10 minutes.

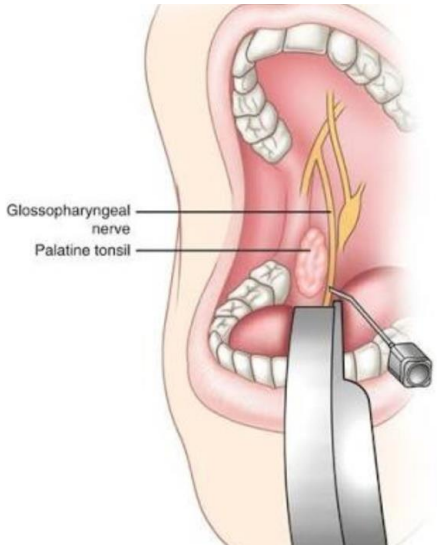


Figure showing glossopharyngeal nerve block

The transtracheal block is usually done just prior to start of FOB intubation. The procedure involves taking of 2-4ml of 4% lignocaine in 10ml syringe with 23 G needle and cricothyroid membrane is pierced with needle in posterior, perpendicular to the floor direction. A sudden loss of resistance is felt when the needle enters the trachea, after which the local anaesthetic is rapidly injected and needle is quickly withdrawn. A bout of cough suddenly follows which helps spread of local anaesthetics to the entire trachea between carina and vocal cords. The complications of transtracheal block include tracheal injury, subcutaneous emphysema and bleeding.

Figure showing transtracheal block

The superior and inferior laryngeal branches of the vagus supplies sensory innervations of the laryngopharynx . the internal division of the superior laryngeal nerve is sensory to base of the tongue, vallecula, epiglottis, pyriform recess and the laryngeal vestibule above the vocal cords. The recuurent laryngeal nerve, an inferior branch of vagus, is sensory to the area below the vocal cord . the internal branch of superior laryngeal nerve is blocked between the greater cornua of the hyoid bone and the superior cornua of the thyroid cartilage as the nerve passes through the thyrohyoid membrane to the submucosa of the piriform sinus. A 23 G needle with a syringe containing 5ml of 1% lidocaine is inserted until if rests on the lateral most part of the hyoid bone and then it is withdrawn a bit and in the inferior direction, walked off the greater

cornua and advanced through the thyrohyoid membrane, which gives a slightly resistant felt and 2ml of local anaesthetic is injected.

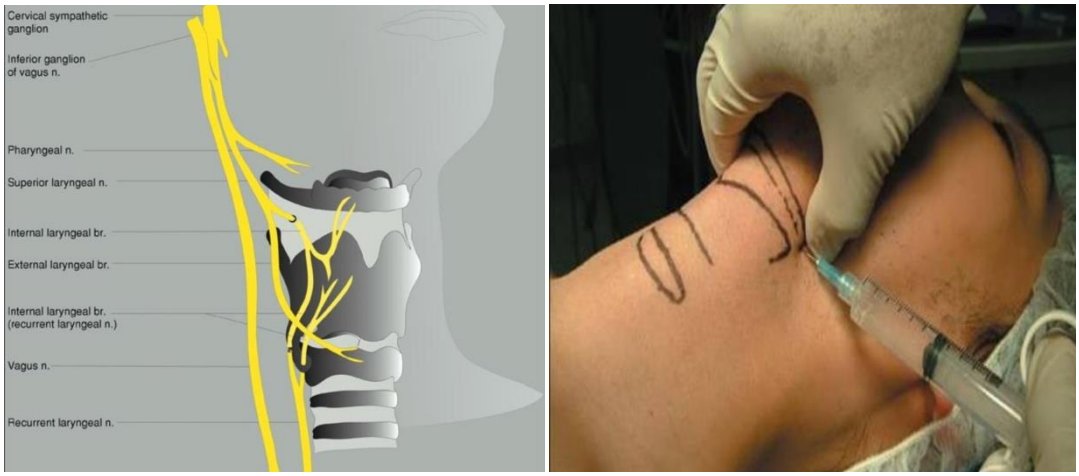


Figure showing nerve supply of larynx and superior laryngeal nerve block

SEDATIVES:

Unless properly sedated intubation is extremely discomforting and unpleasant experience for the patient. Thus the use of sedatives form a vital part of the pharmacological preparation.

Ideal sedative should provide,

Patient comfort and cooperation

Anxiolysis

Amnesia

Attenuated airway reflexes / antitussive properties

Stable hemodynamics

Maintenance of patent airway with spontaneous ventilation.

The available choice of drugs include,

Midazolam	1-2mg
Propofol	25-75µg/kg/min
Dexmedetomidine	0.2-0.7µg/kg/hr
Fentanyl	0.7-1.5µg/kg
Remifentanyl	0.01-0.05 µg/kg bolus followed by 0.03-0.05µg/kg/min
Ketamine	0.025-0.15 mg/kg

The choice and use of above sedatives varies according to the patient and clinical operative settings. For all drugs careful titration should be followed. Extreme caution is warranted when a combination of agent is used as it could be synergetic.

This study aims to test the efficacy of alpha 2 agonist Dexmedetomidine and opioid Fentanyl for sedation during awake fiberoptic intubation.

VASOCONSTRICTORS

When intubation is done through nasal route the vasoconstrictors are administered to reduce the risk of epistaxis. Commonly used drugs include,

Oxymetazoline 0.05%

Xylometazoline 0.1%

Phenylephrine 0.5%

Co-phenylcaine (lidocaine and phenylephrine 0.5%)

Antiemetic such as Ondansetron is used to reduce gag reflex during the procedure.

The nasal mucosa is anaesthetised and vasoconstricted by packing them with swabs soaked in either a 4% cocaine solution or a combination of lidocaine and phenylephrine (1cc of phenylephrine 3 cc of lidocaine). Vasoconstrictors should be cautiously used in pregnant patients due to risk of uteroplacental perfusion reduction and in patients with cardiovascular diseases due to risk of angina pectoris and myocardial infarction (9, 10)

INTUBATION USING THE FIBEROPTIC BRONCHOSCOPE

Once the patient and the airway is prepared as described previously, the anesthetist has to decide whether a nasal or oral approach to be used. In general the nasal route is easier for fiberoptic bronchoscope intubation because the angle or curvature of the endotracheal tube naturally coincide with that of the patients upper airway. Thus it becomes easy to maintain a midline position and direct the scope into trachea (11).

The advantages in a nasal route include reduced gag reflex, free from biting/chewing of the scope by the patient. On the other hand there are risks of bleeding when the nasal route is used.

With the table or bed position at its lowest setting, the patient is kept supine. A step stool is used to keep the FOB straight. The next steps are as follows,

1. An endotracheal tube made up a polyvinyl chloride, which is atleast 1.5mm larger than the diameter of the insertion cord of the insertion cord of the Fiberoptic bronchoscope is preloaded on it.
2. For a nasal intubation, coagulation disorders should be ruled out. A well lubricated soft nasal airway can be used to gauge the nasal patency as well as for gradual dilation in a well prepared anaesthetised and vasoconstricted nasal pathway. The nasal airway is

then removed and the Fiberoptic bronchoscope tip can be directly introduced into the nose.

3. The handle of the Fiberoptic bronchoscope is held in non dominant hand and the tip of the fiberoptic bronchoscope is held in the dominant hand as passing/manoeuvring the tip is an intricate process. The tip of the Fiberoptic bronchoscope is held between the thumb and next two fingers of the dominant hand just like holding a pen.

The non dominant hand holding the handle of the Fiberoptic bronchoscope is held high to prevent bending of the insertion cord.

The lever has to be pressed to look up and down and for looking left or right, the grip on the distal FOB insertion is loosened between the thumb and the next two fingers and the handle section in the non-dominant hand is rotated counter clockwise or clockwise respectively. Further for proper identification of structures, the recognizable landmark are kept in the centre of the view along the desired path.

4. The fiberoptic bronchoscope's tip is passed down the nasopharynx, then the uvula and further downwards to the epiglottis, which is the first landmark. The lever in the handle can be pressed to look upwards for visualization of the structures. If the structures are not

identifiable, the bronchoscope is slowly retracted until a recognizable structures is found and then inserted downwards.

5. After the identification of epiglottis, the tip is inserted into the laryngeal opening. If the topical anaesthetics of the airway is not adequate, using the spray as we go technique, 1ml of 2% lignocaine can be instilled through the working port of the fiberoptic bronchoscope. This may precipitate a bout of cough and so prior information must be given to the patient. After 2-3 minutes, the local anaesthetics act and the tip is further introduced into the subglottic space.
6. Once in the subglottic space, the trachea which is the second landmark is confirmed by the presence of tracheal rings. Once trachea is identified a further 1ml of 2% lidocaine is instilled.
7. After the anaesthetisation of tracheal mucosa, the tip of bronchoscope is pushed downwards until the bifurcation of trachea the carnia is visualised. The carina is the third landmark in the intubation procedure. Another dose of local anaesthetic is instilled.
8. After 1-2 minutes the preloaded endotracheal tube is slided forward on the insertion cord of the Fiberoptic bronchoscope with the murphys eye oriented anteriorly to prevent it from getting hung up on arytenoids. An important aspect that should be noted is that the Fiberoptic bronchoscope should not be allowed to go forward as the

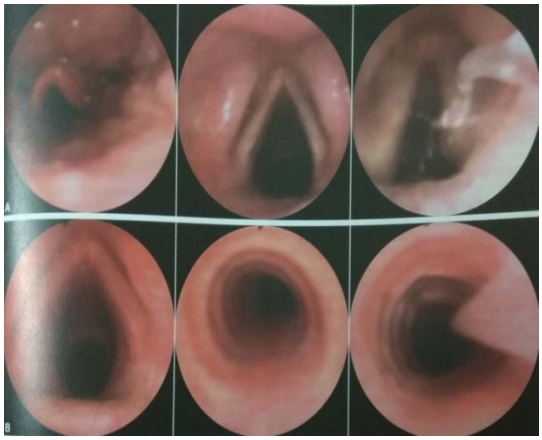
ETT slides forward. This can be ensured by keeping the bifurcation in the view at all times.

9. The breathing sounds of the patient are listened to judge when the ETT is near the larynx. The patient is then asked to take some deep breaths so that the vocal cords move away to admit admit the ETT. Once the ETT has gone beyond the vocal cords into the trachea, the fiberoptic bronchoscope's tracheal view can be obtained.
10. The endotracheal tube is further slided forwards upto two or three rings above the carina. The cuff of the ETT is inflated and the ETT is stabilised in the trachea.
11. The fiberoptic bronchoscope is removed with tip in the neutral position once the endotracheal tube is stabilised. The tip in the neutral position while retraction prevents damage. Once the bronchoscope is removed the ventilating system is attached to the endotracheal tube and the further steps in the general anaesthesia can be initiated. This marks the end of intubation procedure. The end tidal CO2(ETCO2) should be monitored

While the fiberoptic bronchoscope is slided forward into the airway, if there are excessive oropharyngeal secretions or blood obscuring the view, suction can be applied continuously or intermittently providing a clear view.


Xylocaine Jelly 2%
lidocaine hydrochloride
30 g
AstraZeneca


50 ml
Xylocaine®
lidocaine
(10 mg/dose)
Pump Spray
Pump spray for anaesthesia of mucous membranes
Manufactured by:
AstraZeneca AB
151 85 Södertälje, Sweden
Imported by:
PT AstraZeneca Indonesia
Cikarang, Bekasi - Indonesia
AstraZeneca



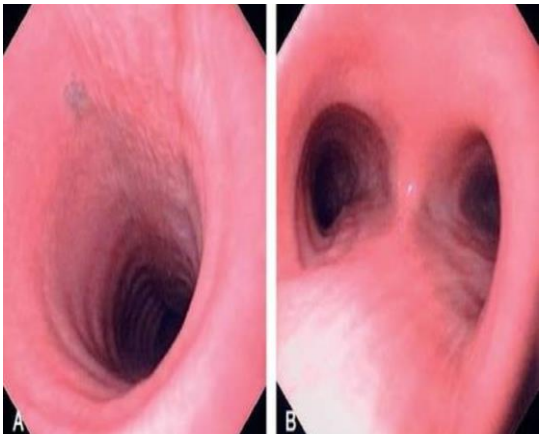


Figure showing Steps of fiberoptic bronchoscope intubation

If the tip of fiberoptic bronchoscope gets fogged due to warm exhaled air, defogging can be done by touching the tip of FOB onto the mucosa or by removing and dipping into warm saline solution.

If the cough or gag is persistent as the fiberoptic bronchoscope is advanced, the local anesthetic blocks has to be repeated or the “spray as you go” technique can be used.

Care should be taken to ensure that all the vital parameters of the patient including blood pressure, heart rate, oxygen saturation, ECG are monitored continuously and are within acceptable limits.

The fiberoptic bronchoscope intubation can be combined with other devices so that better airway control, higher rate of success, reduction of failed intubation can be achieved. The combination devices include,

a. Endoscopic masks
b. Nasopharyngeal airways
c. Supraglottic airway devices like laryngeal mask airway (LMA).

Endoscopy masks allow for spontaneous or controlled ventilation while both nasal and oral intubation can be performed. They have a port

for allowing FOB to pass through a diaphragm which is airtight preventing airleak while ventilating the patients.

The use of short and soft nasopharyngeal airway helps in gradual dilation of nostrils after proper lubrication and facilitates the subsequent pass through of the fiberoptic bronchoscope.

Intubating supraglottic airway device acts as a conduit for blind passage of an ETT into the trachea. The success rate for FOB-intubating SGA combination is greater than 98%.

COMPLICATIONS OF FOB INTUBATION:

The various complications that are commonly encountered in FOB intubation include,

- Nasal bleeding/epistaxis
- Tissue trauma
- Hoarseness of voice
- Sore throat
- Laryngospasm and bronchospasm
- Aspiration
- Damage to bronchoscope by chewing, biting etc, (12).

PHARMACOLOGICAL REVIEW

This dissertation aims to compare the efficiency of two drugs,

1. Dexmedetomidine

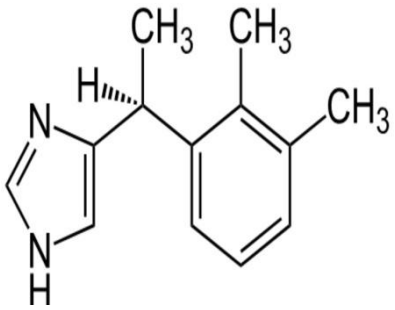
2. Fentanyl

For sedation during awake fiberoptic intubation.

DEXMEDETOMIDINE:

It is a potent alpha-2 adrenergic agonist. It was approved by FDA in 1999 for use in humans as analgesic and for ICU sedation and in 2008 for sedation in non-intubated patients.

STRUCTURE:



Dexmedetomidine is chemically described as (+)-4-(S)-[α-(2,3-dimethyl)ethyl]H-Imidazole monohydrochloride

It has molecular weight of 236.7

Its empirical formula is C13H16N2.HCL

The Pka of Dexmedetomidine is 7.1

PRESENTATION:

Trade names under which Dexmedetomidine hydrochloride are marketed include precedex, dexdor, and dexdomitor.

Dexmedetomidine hydrochloride is a sterile, nonpyrogenic solution suitable for intravenous infusion.

DOSE:

Dose of Dexmedetomidine for sedation is,

Loading dose-1µg/kg over ten minutes

Maintenance dose-0.2 to 0.7 µg/kg/hour

For patients over 65 years of age, dose reduction should be considered.

In this study Dexmedetomidine is used at a dose of 1µg/kg given as a loading infusion.

POTENCY:

Dexmedetomidine is a potent alpha-2 adrenergic agonist which is shorter acting than clonidine. It is much more selective for α2 vs. α1receptors than clonidine.

Dexmedetomidine- 1620:1(13)

Clonidine- 220:1

MECHANISM OF ACTION:

Dexmedetomidine is a highly selective potent α2 adrenergic agonist. It has sedative, analgesic, anxiolytic and anti sialogouge properties with minimal respiratory depression.

Dexmedetomidine acts upon the pontine locus ceruleus which is an important centre for sympathetic system function, vigilance, analgesia and arousal. The sedation, analgesic effect produced is largerly due to the inhibition of this nucleus.

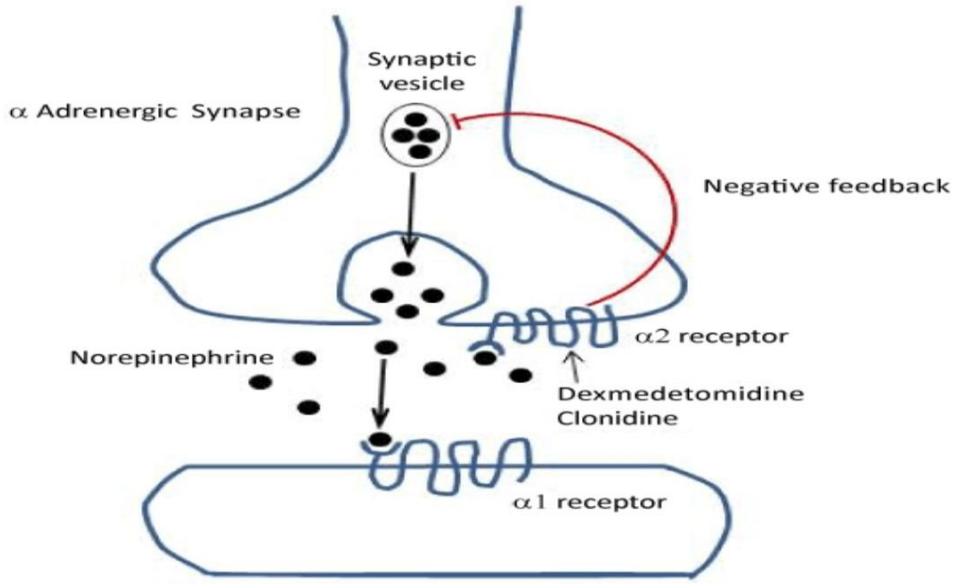
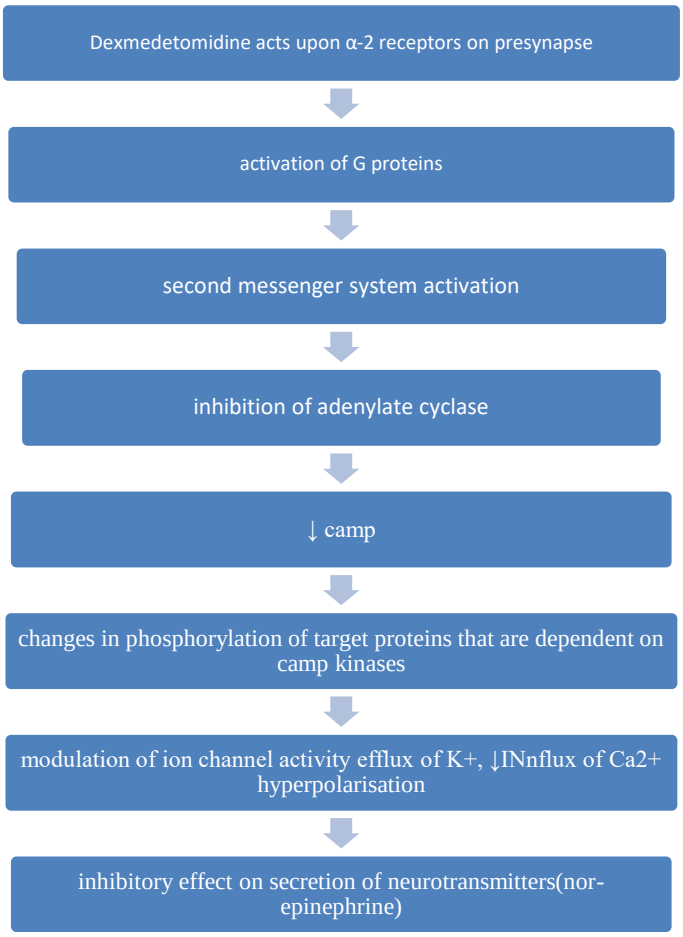


Figure showing mechanism of action of dexmedetomidine



PHARMACOKINETICS:

Dexmedetomidine has a rapid distribution phase, with a distribution half life of approximately six minutes, and terminal elimination half life of approximately 2 hours

Peak plasma concentration-0.3 to 0.5 ng/ml.

Protein bound-94%

Volume of distribution 118 L.

METABOLISM:

Dexmedetomidine is metabolised by liver via glucuronidation and CYP2-A6

Metabolites include 3-hydrox,3-carboxy, 3- hydroxyl N-methyl, 3-carboxy N-methyl and N-methyl O-glucuronide Dexmedetomidine.

Total body clearance-39L/hr.

Excretion –urine (95%)

Feces (4%).

EFFECTS:

CENTRAL NERVOUS SYSTEM:

Presynaptic action of α-2 receptors inhibits the release of norepinephrine thereby terminating the propagation of pain signals. Post synaptic activation of α-2 receptors in the CNS inhibits sympathetic activity. Combained these effects produce analgesia, sedation and anxiolysis (14).

The sedation produced by α-2 agonists differ from sedation produced by drugs like midazolam that act on GABA receptors. α-2 agonists decrease sympathetic system activity and level of arousal. This provides a calm patient who can be easily aroused to full consciousness.

On the other hand, drugs acting upon GABA produce a clouding of consciousness and can also cause paradoxical agitation as well as tolerance and dependence (15).

CARDIOVASCULAR SYSTEM:

Higher concentration of Dexmedetomidine causes bradycardia and a biphasic dose-response relation for mean arterial pressure.

Premedication with Dexmedetomidine attenuates the hemodynamic responses to endotracheal intubation and decreases plasma catecholamine levels.

RESPIRATORY SYSTEM:

Dexmedetomidine does not cause clinically relevant respiratory depression or exhibits only minimal respiratory depression unlike other opioid sedatives. This unique feature enables it to be used as a sedative for patients with difficult airway during AFOI, in mechanically ventilated patients in intensive care units.

Dexmedetomidine decreases the mean alveolar concentration (MAC) for volatile anaesthetics. Isoflurane MAC was decreased 35% and 48% by Dexmedetomidine plasma concentration of 0.3ng/ml and 0.6ng/ml respectively (16).

GASTROINTESTINAL SYSTEM:

Reduced salivary secretion-anti sialogouge property enables clear visualisation of airway structures.

Decrease bowel motility.

EXCRETORY SYSTEM:

Inhibition of rennin release.

Increased glomerular filtration rate.

Increased secretion of sodium and water in the kidney.

ENDOCRINE CHANGES

Decreased insulin release from the pancreas (17).

DRUG INTERACTION:

Dexmedetomidine may enhance the effects of other sedatives and anaesthetics when co-administered

Drugs that reduce heart rate and blood pressure like β-blockers should be cautiously used when co administered with Dexmedetomidine.

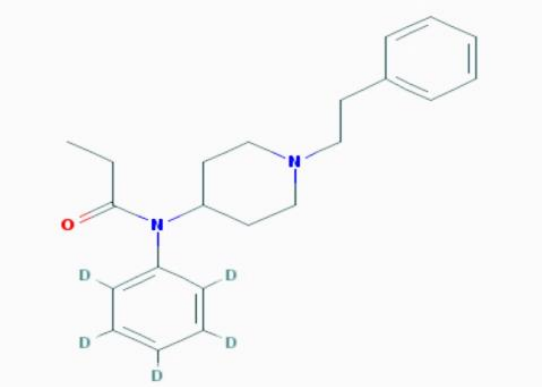
ANTAGONISTS:

Atipamezole is a specific and selective α-2 receptor anatagonist that effectively and rapidly reverses the sedative and cardiovascular effects of intravenous Dexmedetomidine (18).

FENTANYL:

Fentanyl is a synthetic opioid, a tertiary amine and phenyl piperidine derivative.

STRUCTURE:



Molecular formula-C22H28N2O

Molecular weight-336.479 g/mol

Fentanyl is chemically described as N-(1-Phenyl-4-piperidyl) propionanilide hydrochloride.

Pka of Fentanyl-8.4.

PRESENTATION:

1. Fentanyl is available as transdermal patches at various doses 25/50/75/100 µg delivered per hour over a period of 72 hours.

2. As a clear, colourless solution for injection containing 50µg/ml of Fentanyl citrate.

3. Fentanyl citrate is also available as lollipop sticks which slowly dissolve in mouth-in dosages 200µg, 400µg, 600µg, 800µg, 1200µg and 1600µg.

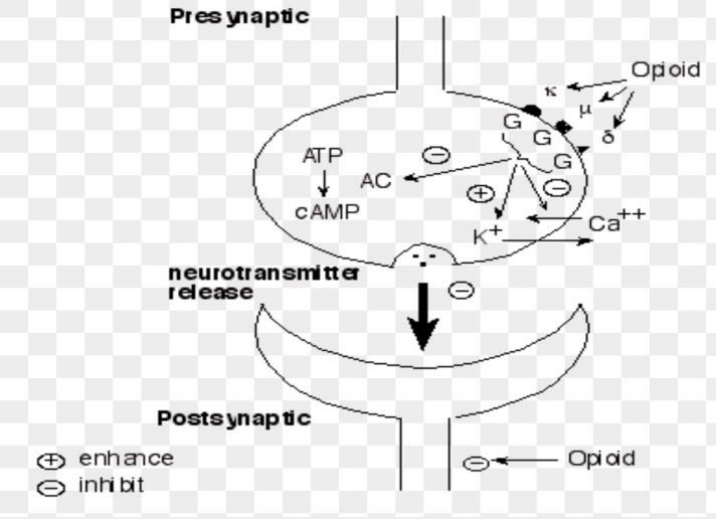
ANALGESIC PROPERTY:

Fentanyl is 1000 times more potent than Meperidine (19), 75-125 times more potent than Morphine.

100µg of Fentanyl is equal to 75mg of Meperidine, 10mg of Morphine.

MECHANISM OF ACTION:

Fentanyl is a highly selective opioid µ receptor agonist which is mainly responsible for producing its analgesic property. Fentanyl increases intracellular calcium concentration which in turn increases K+ conductance and hyperpolarisation of cell membrane. This results in decreased membrane conductance in both pre and post synaptic responses. Analgesia is produced principally through interaction with µ receptors at supraspinal levels. Fentanyl can also bind to K receptors resulting in spinal analgesia, sedation and anaesthesia.



PHARMACOKINETICS:

A single dose of Fentanyl administered intravenously has a rapid onset and shorter duration of action than Morphine. There is a distinct time lag between the peak plasma Fentanyl concentration and peak lowing on the EEG reflecting the delay due to effect site equilibrium time between blood and brain for Fentanyl which is 6.4 minutes.

Fentanyl has a greater lipid solubility resulting in greater correlation between plasma concentration of Fentanyl with that of CSF concentration.

The rapid distribution to inactive tissue sites accounts for its shorter duration of action. 75% of the initial dose undergoes first pass pulmonary uptake (20). This limits the initial amount of drug that reaches the systemic circulation and may play an important role in determining the pharmacokinetic profile of Fentanyl.

Fentanyl has a longer elimination half life than Morphine.

The volume of distribution is 0.88-4.4L/kg.

METABOLISM:

Fentanyl is extensively metabolised by N-demethylation producing norfentanyl, hydroxypropionyl Fentanyl and hydroxypropionyl-norfentanyl.

Norfentanyl is the principal metabolite of Fentanyl in humans. Other metabolites have minimal pharmacological activity.

Cytochrome P-450 3A4 plays predominant role in Fentanyl metabolism (21).

EXCRETION:

Around less than 10% of Fentanyl is excreted unchanged in urine.

Clearance is 0.4-1.5L/Min.

Clearance is decreased in patients with hepatic impairment.

EFFECTS:

RESPIRATORY SYSTEM:

Fentanyl at 1-2µg /kg decreases respiratory rate and increases tidal volume When doses are increased above 3µg/kg it decreases both

respiratory rate and tidal volume and ventilator response to hypoxia and hypercarbia.

When large doses are given rapid IV it can produce chest wall rigidity, due to its effect on μ receptors located on GABA interneurons. Can be controlled by use of muscle relaxants.

CENTRAL NERVOUS SYSTEM:

It is a CNS depressant.

In low doses 1-2μg/kg it is devoid of hypnotic and sedative activity.

Fentanyl produces miosis due to stimulation of Edinger Westphal nucleus.

CARDIOVASCULAR SYSTEM:

DOSE	CARDIOVASCULAR EFFECTS
1μg/kg	No significant effect on papillary muscles
7μg/kg	↓heart rate
10μg/kg	Myocardial contractility reduced by 50%
20-25μg/kg	↓ hear rate, MAP, systemic and pulmonary vascular resistance
75μg/kg	Hemodynamic stability

Table 1

GASTROINTESTINAL TRACT:

Fentanyl increases common bile duct pressure by causing spasm of sphincter of oddi.

It causes nausea, vomiting and decreases GI motility.

GENITOURINARY SYSTEM:

It increases the tone of the ureters, bladder detrussor muscle and vesicle sphincter causing retention of urine.

METABOLIC EFFECTS:

Fentanyl increases plasma epinephrine, cortisol, glucose, free fatty acids and growth hormone levels during surgery.

RELATIONSHIP BETWEEN PLASMA FENTANYL CONCENTRATION AND EFFECT (22)

PLASMA FENTANYL CONCENTRATION(ng/ml)	PHARMACOLOGICAL EFFECT
>1	Slight analgesia and minimal ventilatory depression.
1-3	Analgesia, 50% decrease in ventilatory response to Co2.
4-10	Analgesia for surgery if combined with N2O.
>20	Unconscious, satisfactory as sole agent.

Table 2

SIDE EFFECTS:

The main side effect of concern is respiratory depression, intraoperatively and postoperatively (23) due to which continuous monitoring is warranted.

Respiratory depression is related to secondary peak in plasma Fentanyl concentration due to elution from muscle.

Others are nausea, vomiting, pruritis, urinary retention, dependence etc..,

DRUG INTERACTION:

When Fentanyl is combined with benzodiazepines there is a marked synergism in hypnosis and depression of ventilation (24). In clinical practise adequate caution is required when co administered.

CLINICAL REVIEW:

In a study 60 patients undergoing awake fiberoptic intubation were divided into two groups. Group A receiving Dexmedetomidine at 1µg/kg over 10 mins and group B receiving Fentanyl at 2 µg/kg over 10 minutes for sedation during intubation. They concluded that Dexmedetomidine is more effective than Fentanyl in producing better intubating conditions, sedation, hemodynamic stability and less desaturation during AFOI (25).

In a study 40 patients with anticipated difficult airway and to undergo tracheal intubation for elective surgery were randomly divided into Dexmedetomidine group 1µg/kg over 10 minutes and propofol target controlled infusion group. They concluded that both Dexmedetomidine and Propofol TCI are effective for fibroptic intubation but Dexmedetomidine allows better tolerance, hemodynamic status and preserves a patent airway (26).

In a study 55 patients were divided into two groups with one group receiving Dexmedetomidine with Midazolam 0.02mg/kg and other group receiving Midazolam alone @0.05mg/kg for sedation. They concluded that patients who received Dexmedetomidine and Midazolam were significantly calmer and cooperative during AFOI, more satisfaction with fewer adverse effects and no significant hemodynamic differences than Midazolam only group (27).

In a study, 30 oral carcinoma patients with limited mouth opening undergoing AFOI for elective surgery were divided into two groups. The DEX group with 16 patients received Dexmedetomidine 1µg/kg and the Fentanyl group with 14 patients received Fentanyl at a dose of 1 µg/kg. They concluded that Dexmedetomidine with topical anaesthesia provides significant benefits for AFOI in intubating conditions, patient tolerance, hemodynamic response, amnesia and satisfaction (28).

In a study four patients with particularly difficult airway underwent AFOI with Dexmedetomidine. They reported that Dexmedetomidine provides a moderate level of conscious sedation without causing respiratory distress or hemodynamic instability during fibroptic intubation (29).

In a study three patients undergoing cervical spine surgery under AFOI with Dexmedetomidine sedation reported that intubating conditions were acceptable with Dexmedetomidine and topical anaesthesia (30).

In a study three patients with odontogenic and cervical infection undergoing AFOI were sedated with Dexmedetomidine. They reported that Dexmedetomidine provided safe and effective sedation and anxiolysis (31).

In a study, a patient with cervical cord compressive lesion and raised intracranial pressure undergoing elective excision of a cerebellopontine angle lesion had AFOI under Dexmedetomidine sedation. They reported Dexmedetomidine facilitated self positioning before surgery and no adverse neurological outcomes were reported (32).

In a study 56 patients undergoing cervical fixation were divided into two groups of 26 patients for AFOI. The test group received Dexmedetomidine infusion and the control group received normal saline.

They reported that group receiving Dexmedetomidine infusion in addition to topical anaesthesia during AFOI remained more comfortable than group with airway block alone (33).

In a stud a total of 90 patients, all ASA PS – I, II undergoing AFOI were divided into two groups. One group received remifentanyl and other group received Dexmedetomidine sedation. Both group received 2% lignocaine for topical anaesthesia. They concluded that comfort scales and airway events did not differ significantly between the two groups, Dexmedetomidine and Remifentanyl exhibit similar efficacy as adjuvant therapies for AFOI (34).

METHODOLOGY

Study Pattern:

This clinical study was conducted in the Department of Anesthesiology in association with Department of General Surgery, ENT in Govt. Theni Medical College, Theni between 01.08.2017 to 01.08.2018. Necessary clearances were obtained from the Hospital ethics committee for the study. Written Informed consent was obtained from all patients.

A total of 60 patients posted for elective surgery undergoing Awake Fiberoptic Intubation were included.

Patient Selection:

Inclusion Criteria:

i. Age Group 18 – 50 years

ii. ASA – PS I and II

iii. Mallampati Grading I & II

Exclusion Criteria:

- Patients unwilling for the procedure
- Uncontrolled seizure disorder
- History of Unstable Angina or MI/Complete Heart block

- Resting Heart Rate < 50/min
- History of allergy to Local Anaesthetic drug
- History of bleeding disorders
- Diabetes Mellitus/Systemic Hypertension
- History of Psychiatric/Neurological disease
- MPG III and IV

Equipments:

1. IV canula and IV fluids
2. Fiberoptic Bronchoscope of appropriate size
3. Endotracheal tube of appropriate size
4. Drugs

    Study agent

    Inj. Dexmedetomidine

    Inj. Fentanyl

    Emergency drugs

        Inj. Adrenaline

        Inj. Atropine

        Inj. Ephedrine

Inj. Thiopentone Sodium/Inj. Propofol

Inj. Succinyl choline

Others

i. Inj. Metoclopramide
ii. Inj. Ranitidine
iii. Inj. Ondansetrone

5. Boyle's Machine
6. Resuscitation equipments, Oxygen cylinder, AMBU bag, Laryngoscope, Endotracheal tubes of different sizes, Suction apparatus, and Emergency tray.
7. Monitoring equipment ECG, NIBP, Pulse Oximetry.

Methodology:

A total of 60 patients with ASA I & II and Mallampati grading I & II who were posted for elective surgery like laparoscopic appendicectomy, laparoscopic cholecystectomy, Thyroidectomy, Parotidectomy, modified radical mastoidectomy, were selected for the study according to the inclusion & exclusion criteria. A well informed written consent was obtained from all of them.

A detailed history, physical examination and routine investigations were done for all the patients. IV line was secured with a 18G Cannula.

All vital parameters (HR, NIBP, Respiratory Rate, O_2 Saturation, and ECG) were being continuously monitored. Baseline heart rate and Mean Arterial pressure readings were taken.

Patients were randomly allocated into two groups,

i. Group A – Receiving Inj. Dexmedetomidine at a dose of 1ug/kg over 10 min
ii. Group B – Receiving Inj. Fentanyl at a dose of 2ug/kg over 10 min

The total dose of the drug was calculated according to the patient's weight.

All patients had premedication drugs with tab Alprazolam 0.5 mg night before surgery, tab Ranitidine 150 mg and tab Ondansetron 4 mg on the morning 2 hours before the surgery Inj. Glycopyrrolate 0.2 mg IV was given. Topicalisation of upper and lower airway was accomplished by nebulisation with 4% lidocaine 4ml (160mg) for 20 min. Patency of both nostrils were tested and nostril with better patency was chosen for Awake Nasal Fiberoptic Intubation. Xylometazoline nasal drops and lidocaine Jelly were applied to both the nostrils. Oropharynx and Hypophranynx were sprayed with two puffs of 10% lidocaine (20mg). Then as per the patient's grouping, Inj. Dexmedetomidine (1ug/kg over 10 min) or Inj.

Fentanyl (2ug/kg over 10 min) were infused. At the end of study drug Infusion, the level and quality of sedation was assessed using Ramsay sedation scale/score. A well lubricated Fibreoptic bronchoscope preloaded with appropriate size cuffed Endotracheal tube was kept ready.

- The grading of sedation as per RAMSAY SEDATION SCORE are as follows:

  1. Anxious, Agitated or Restless
  2. Cooperative, oriented and tranquil
  3. Sedated but responds to command
  4. Asleep, brisk glabellar reflex, responds to loud noise
  5. Asleep, Sluggish glabellar reflex, responds to loud noise
  6. Asleep with no response to a painful stimulus

  After achieving RSS>= 2, bronchoscopy was performed through Nasal approach. If RSS >=2 could not be achieved after the infusion of the study drug Inj. Midazolam 0.05mg/kg was used as rescue sedation.

- Intubation condition was evaluated by COUGH SCORE during bronchoscopy

  Score 1 – no cough

  Score 2 – Slight cough (no more than 2 cough in sequence)

  Score 3 – Moderate cough (3-5 coughs in sequence)

  Score 4 – Severe cough(>5 Coughs in sequence)

- Tolerance to intubation was evaluated by the POST INTUBATION SCORE after the successful placement of endotracheal tube in the trachea.

  Score 1 - Co-operative

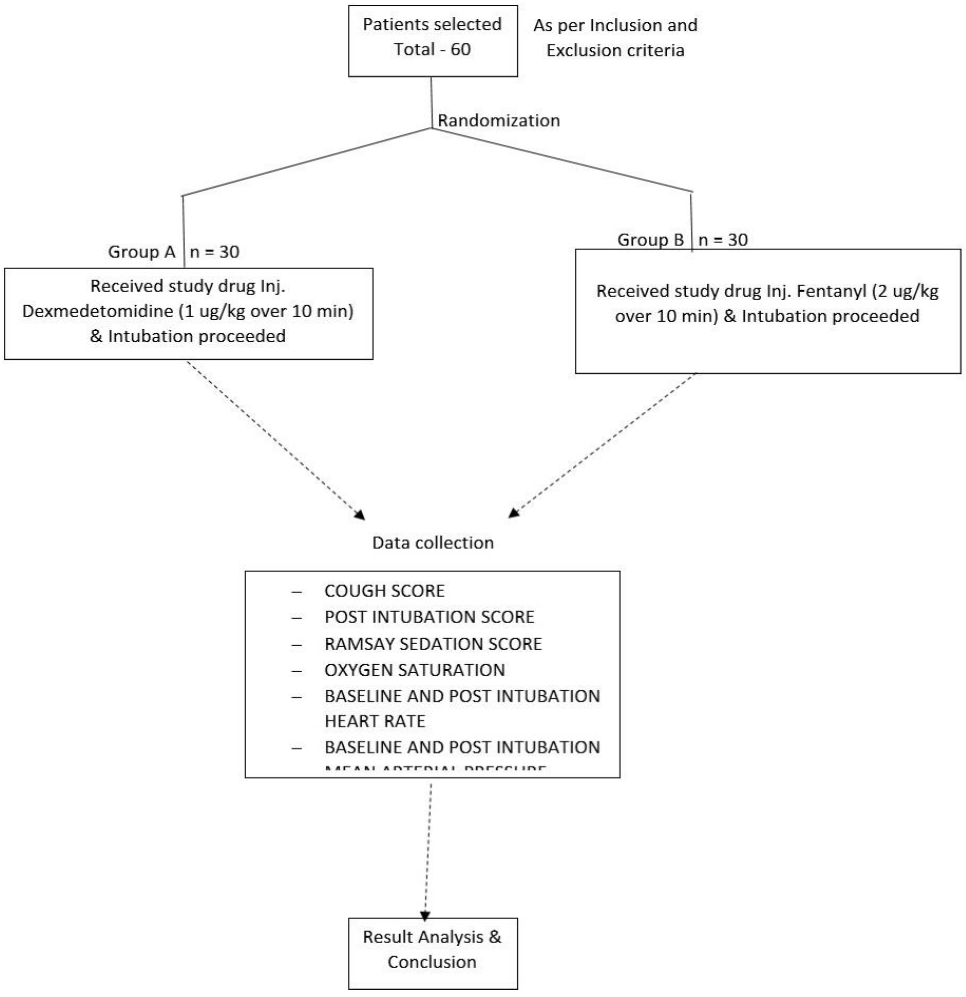
  Score 2 – Minimal Resistance

  Score 3 – Severe resistance

- Further, Heart rate and Mean Arterial Pressure were noted immediately after intubation
- Oxygen saturation using SpO_2 was monitored throughout the procedure and the lowest reading was noted.
- After proper placement of ETT in trachea, general anesthesia was induced and surgery was allowed to proceed.
- During the intubation and post intubation periods, Hypotension, Bradycardia and Desaturation were promptly corrected under relevant protocols. Hypotension (Decrease in MAP > 20% from baseline) was treated with IV fluids and Inj. Ephedrine 6mg IV in titrated doses.
- Oxygen desaturation (SPO_2< 95% for > 10 seconds) was treated with O_2 supplementation. Brady cardia (HR < 60 /min) was treated with Atropine.
- All recordings were tabulated. Numerical data were expressed as mean with a standard deviation. The necessary statistical analysis

was carried out using the statistical package for the social sciences 20.0 statistical software package. Numerical data were compared between the 2 groups using independent t-test and within the same group using paired t-test. Categorical data were compared between two groups using chi square test. P value < 0.05 was considered statistically significant. Further, for better understanding, necessary data's are also expressed in bar diagrams.

The following flow chart explains the progress of participants through the study.



OBSERVATION AND RESULTS

The master chart detailing the age and sex of the patients involved in the study, their weight, ASA-PS, categorisation as group-A and group-B, cough score, post intubation score, Ramsay sedation score, oxygen saturation, baseline and post intubation heart rate, baseline and post intubation mean arterial pressure is added in annexure.

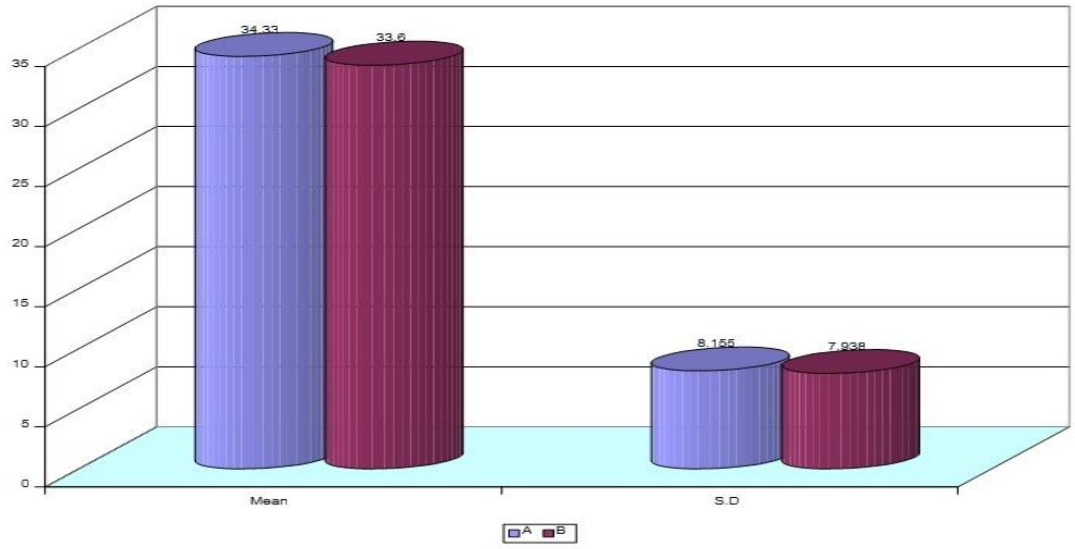
AGE DISTRIBUTION:

Table 3:

T-Test

Age	n	Mean	S.D	T	Df	Statistical inference
A	30	34.33	8.155	0.353	58	.725>0.05 Not Significant
B	30	33.60	7.938			

Diagram



The age data of the patients in group-A and group-B were analysed using t-test. In group-A (n=30), the mean age was 34.33 years with a standard deviation of 8.155 years. In group-B (n=30) the mean age was 33.60 years with a standard deviation of 7.938 years. The P value was 0.725 which is greater than 0.05 and hence the age correlation between the two groups is statistically not significant.

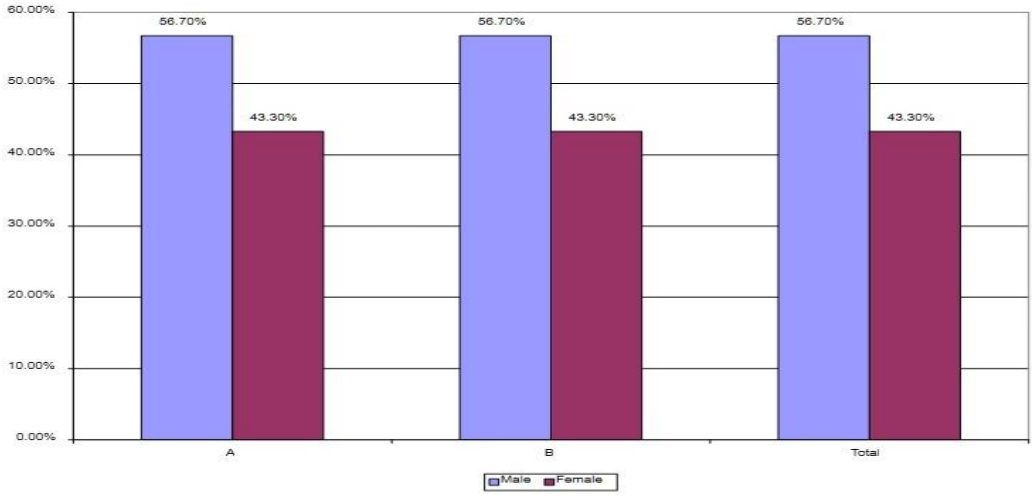
SEX DISTRIBUTION:

Table 4:

Chi-square test

Sex	A - Group		B - Group		Total		Statistical inference
	n	*%*	*n*	*%*	*n*	*%*	
Male	17	56.7%	17	56.7%	34	56.7%	X^2=0.000 Df=1 1.000>0.05 Not Significant
Female	13	43.3%	13	43.3%	26	43.3%	
Total	**30**	**100.0%**	**30**	**100.0%**	**60**	**100.0%**	

Diagram



The data regarding the sex in both groups were analysed using the chi-square test. In group A (n=30), there were 17 males and 13 females. The composition of males and females in group A were 56.7% and 43.3% respectively. In group-B (n=30) there were 17 males and 13 females. The composition of male and female in group-B were 56.7% and 43.3% respectively. The P value was 1 which is greater than 0.05. Hence the sex correlation between the two groups is statistically not significant.

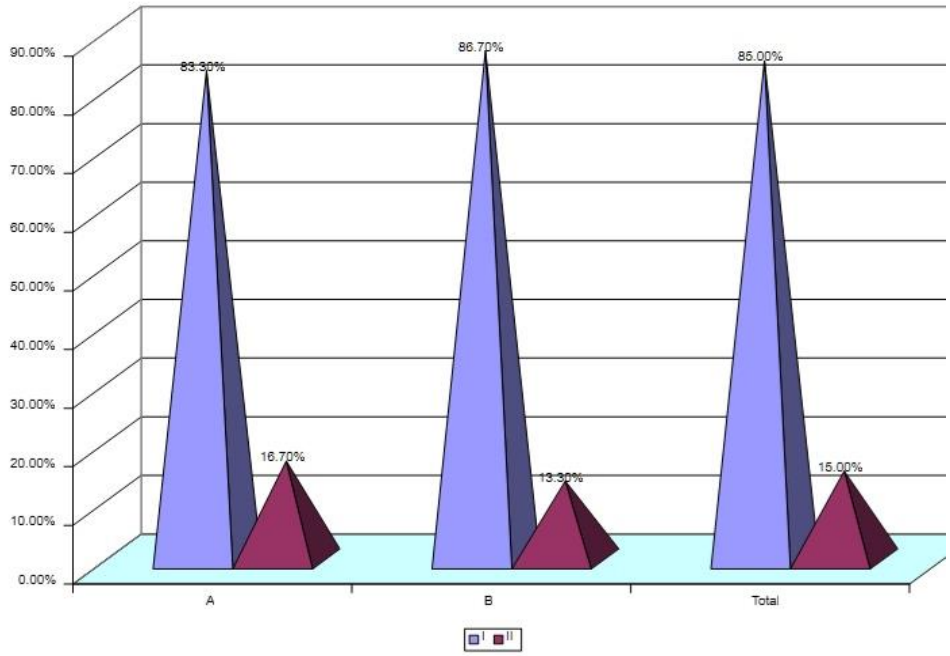
DISTRIBUTION OF ASA-PS

Table 5:

Chi-square test

ASA-PS	A - Group		B - Group		Total		Statistical inference
	n	*%*	*n*	*%*	*n*	*%*	
I	25	83.3%	26	86.7%	51	85.0%	X^2=0.131 Df=1 .718>0.05 Not Significant
II	5	16.7%	4	13.3%	9	15.0%	
Total	**30**	**100.0%**	**30**	**100.0%**	**60**	**100.0%**	

Diagram



The data regarding ASA-PS were analyzed using chi-square test. In group-A (n=30) there were 25 patients with ASA-PS I and 5 patients with ASA=PS-II. The composition of ASA-PS I and II in group A were 83.3% and 16.7%. In group B (n=30) 26 patients with ASA-PS I and 4 patients with ASA=PS –II . The composition of ASA-PS I and II in group B were 86.7% and 13.3% respectively. The P value was 0.718 which is greater than 0.05 hence correlation of the data regarding ASA-PS between the two groups is statistically not significant.

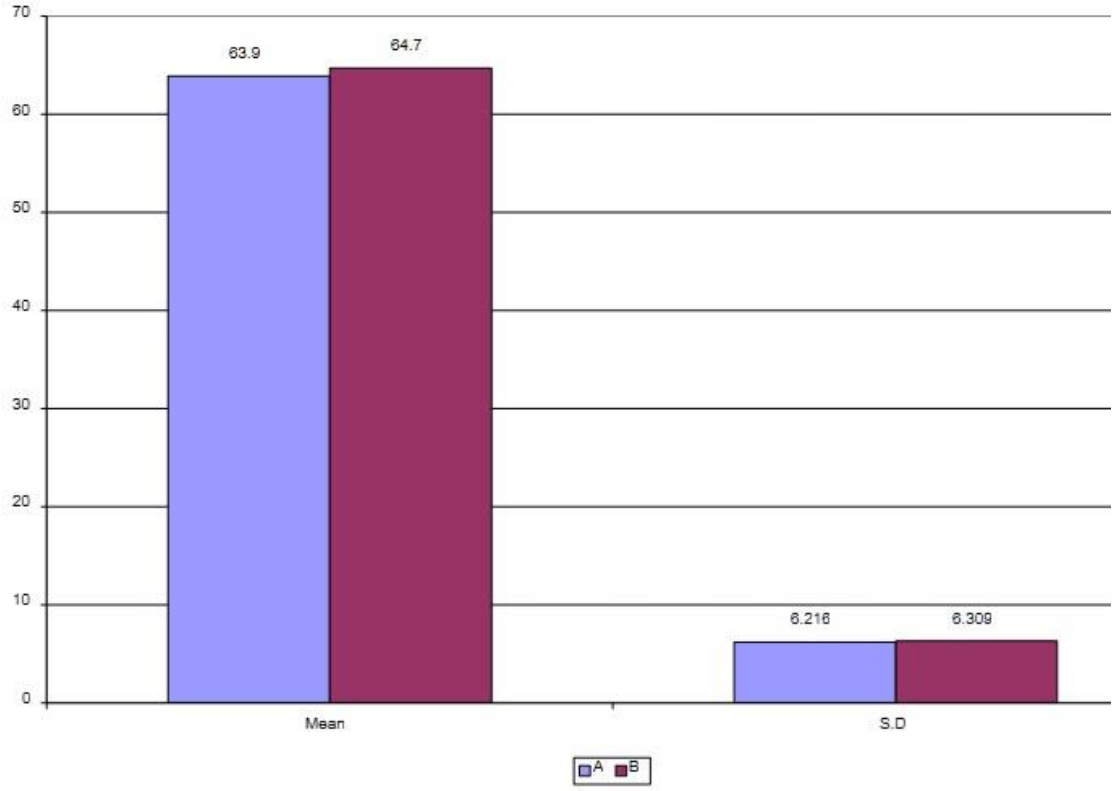
WEIGHT DISTRIBUTION:

Table 6:

T-Test

Weight	n	Mean	S.D	T	Df	Statistical inference
A	30	63.90	6.216	0.495	58	.623>0.05 Not Significant
B	30	64.70	6.309			

Diagram



Weight data in both the groups were analyzed using the t test. In group-A (n=30), the mean weight was 63.90 kg with a standard deviation of 6.216 kg. In group B (n=30), the mean weight was 64.70 kg with a standard deviation of 6.309 kg. The P value was 0.623 which is greater than 0.05. Hence the weight correlation between the two groups is statistically not significant.

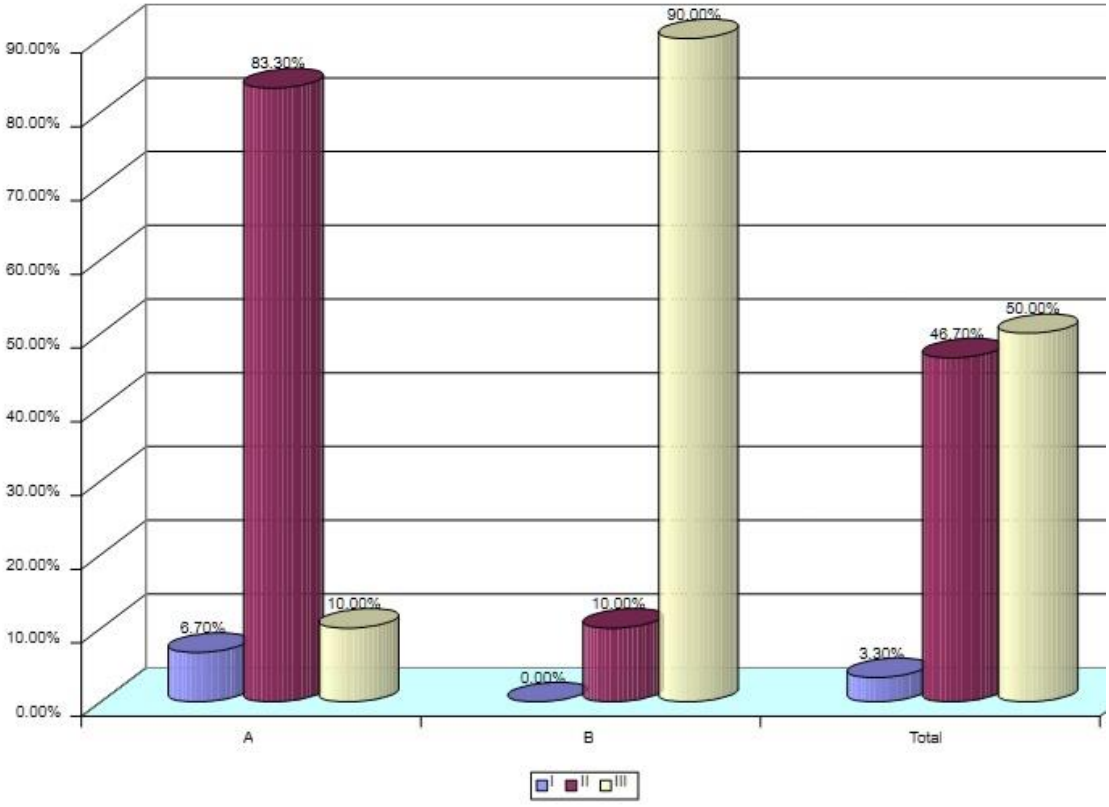
COUGH SCORE DISTRIBUTION:

Table 7:

Chi-square test

Cough Score	A - Group		B - Group		Total		Statistical inference
	n	*%*	*n*	*%*	*n*	*%*	
I	2	6.7%	0	.0%	2	3.3%	X^2=38.486
II	25	83.3%	3	10.0%	28	46.7%	Df=2
III	3	10.0%	27	90.0%	30	50.0%	.001<0.05 Significant
Total	**30**	**100.0%**	**30**	**100.0%**	**60**	**100.0%**	

Diagram



The data regarding cough score in both groups were analyzed using chi-square test

In group-A (n=30) 2 patients had cough score 1

25 patients had cough score 2

3 patients had cough score 3.

In group-B (n=30), no patient had cough score 1

3 patient had cough score 2

27 patient had cough score 3

No patients from both the groups had severe cough (>5 cough in sequence)i.e. cough score 4

83.3% of the patients in group-A had cough score 2 while 90% of the patients in group B had cough score 3

The P value was 0.001 which is less than 0.05 and hence statistically significant

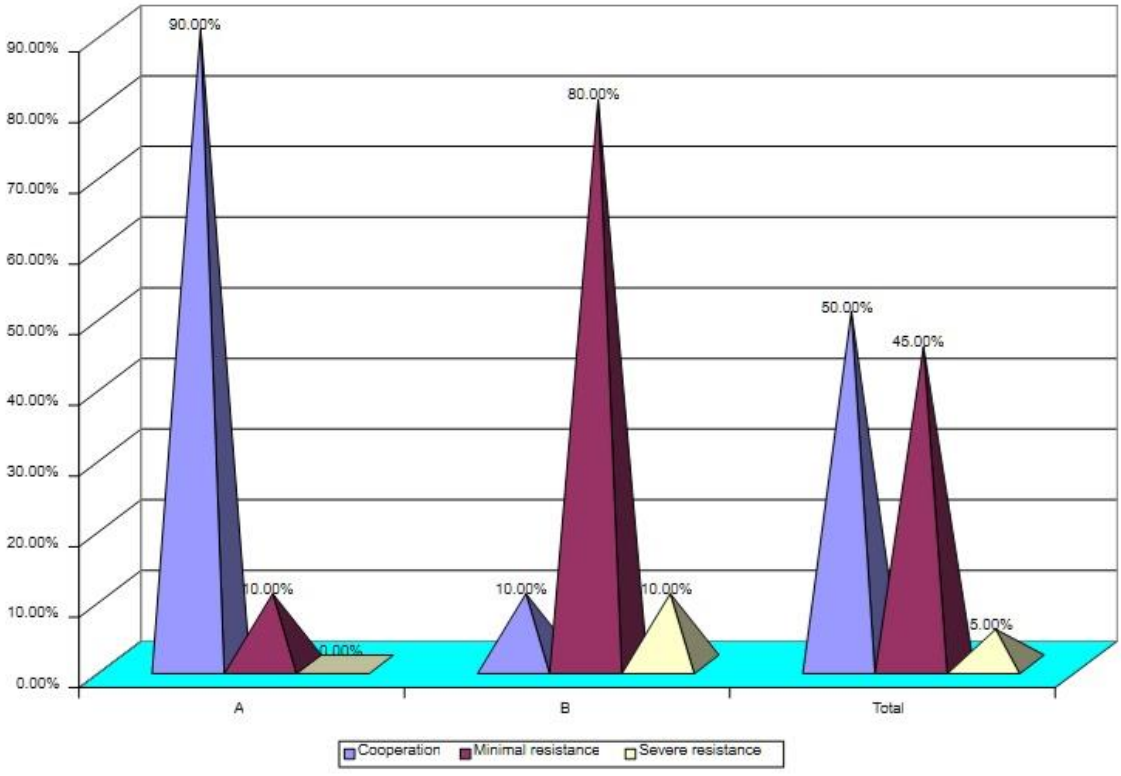
POST INTUBATION SCORE DISTRIBUTION:

Table 8:

Chi-square test

Post Intubation Score	A - Group		B - Group		Total		Statistical inference
	n	*%*	*n*	*%*	*n*	*%*	
Cooperation	27	90.0%	3	10.0%	30	50.0%	X^2=38.533
Minimal resistance	3	10.0%	24	80.0%	27	45.0%	Df=2
Severe resistance	0	.0%	3	10.0%	3	5.0%	.002<0.05 Significant
Total	**30**	**100.0%**	**30**	**100.0%**	**60**	**100.0%**	

Diagram



The data regarding post intubation scores in both groups were analyzed using the chi-square test

In group A (n=30), 27 patients had the best post intubation score 1 (co-operative)

3 patients had the post intubation score 2 (minimal resistance)

No patient had post intubation score 3 (severe resistance)

In group B (n=30), 3 patients had the best post intubation score, score1

24 patients had the post intubation score2

3 patients had the post intubation score3

90% of the patients in group A had the best post intubation score of 1 whereas 80% of the patients in group B had post intubation score 2

P value is 0.002 which is less than 0.05 and hence statistically significant

Thus the post intubation score is significantly favorable in group A than group B.

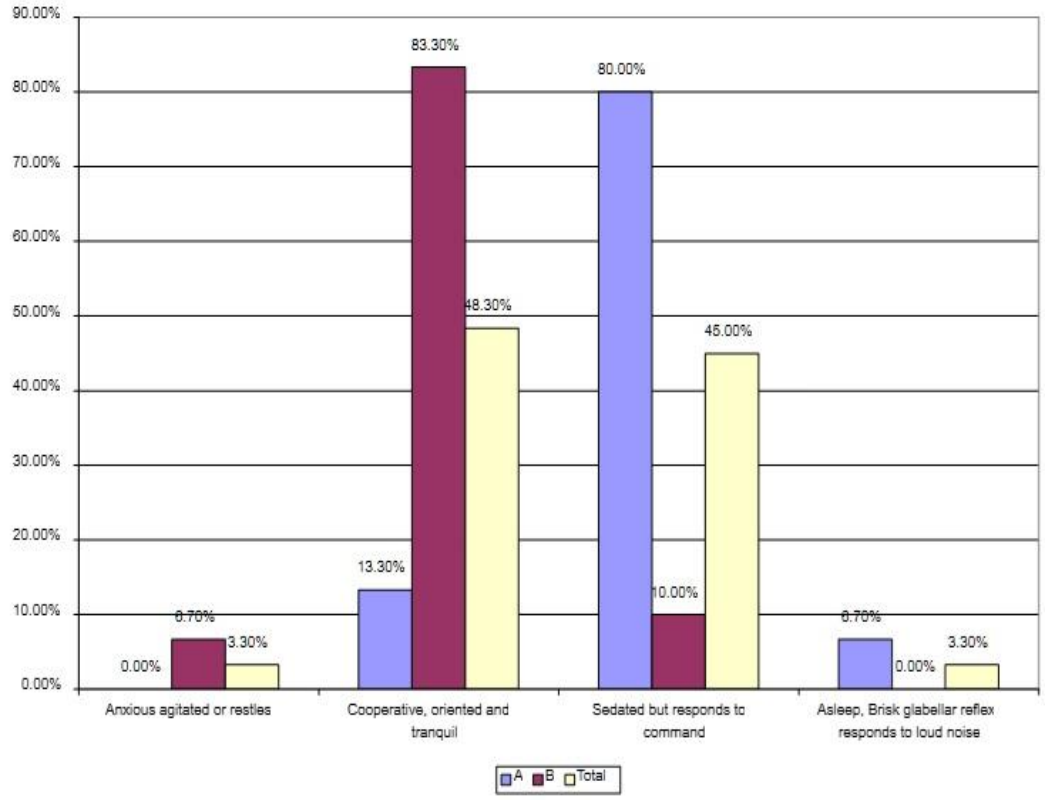
RAMSAY SEDATION SCORE DISTRIBUTION:

Table 9:

Chi-square test

Ramsay Sedation Score	A - Group		B - Group		Total		Statistical inference
	n	%	*n*	%	*n*	%	
Anxious agitated or restles	0	.0%	2	6.7%	2	3.3%	X^2=35.540 Df=3 .00<0.05 Significant
Cooperative, oriented and tranquil	4	13.3%	25	83.3%	29	48.3%	
Sedated but responds to command	24	80.0%	3	10.0%	27	45.0%	
Asleep, Brisk glabellar reflex responds to loud noise	2	6.7%	0	.0%	2	3.3%	
Total	**30**	**100.0%**	**30**	**100.0%**	**60**	**100.0%**	

Diagram



The data regarding the Ramsay sedation score in both groups were analyzed using the chi-square test.

An RSS ≥2 is considered necessary before intubation. If the RSS is < 2 Inj.Midazolam 0.05mg/kg was used as rescue sedation.

In group A (n=30)

- No patient had RSS 1 (Anxious agitated or restless)
- 4 patients had RSS 2 (cooperative, oriented and tranquil)
- 24 patients had RSS 3 (sedated but responds to commands)
- 2 patients had RSS 4(asleep, brisk glabellar reflex, responds to loud noise)

In group B (n=30)

- 2 patient had RSS 1 (Inj.Midazolam 0.05mg/kg was used as rescue sedation)
- 25 patients had RSS 2
- 3 patients had RSS 3
- No patient had RSS 4

Further no patients in both groups had an RSS 5 (asleep, sluggish glabellar reflex, responds to loud noise) or RSS 6 (asleep, no response to painful stimulus)

80% of patients in group A could achieve an RSS of 3 (sedated and responds to commands) while 83.3% of patients in group B achieved an RSS of 2 (cooperative oriented and tranquil)

The P value is 0.004 which is less than 0.05 and hence statistically significant.

Thus Ramsay sedation score is significantly favorable for group A than group B.

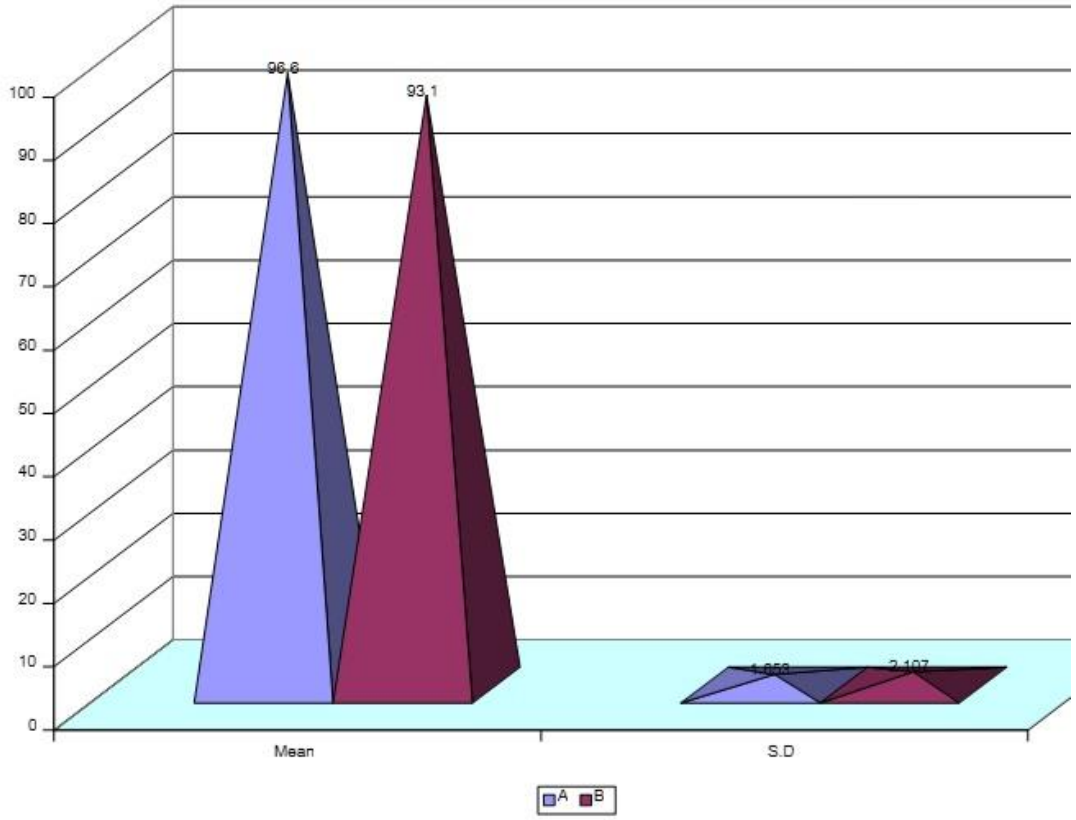
DISTRIBUTION OF OXYGEN SATURATION DATA:

Table 10:

T-Test

Spo2	n	Mean	S.D	T	Df	Statistical inference
A	30	96.60	1.653	7.160	58	.000<0.05 Significant
B	30	93.10	2.107			

Diagram



The data regarding oxygen saturation in both groups were analyzed using t-test

In this study, the SpO2 value which is lowest during the entire intubation procedure (from study drug infusion to completion of intubation) was taken. If SpO2 was less than or equal 95%, it was

considered to be a desaturation event and treated promptly with oxygen supplementation.

In group A (n=30), the mean SpO2 value was 96.6% with a standard deviation of 1.653%

In group B (n=30), the mean SpO2 value was 93.10% with a standard deviation of 2.107%

The P value was 0.000 which was less than 0.05 and hence statistically significant

Thus it can be established that desaturation events were significantly less in group A than group B.

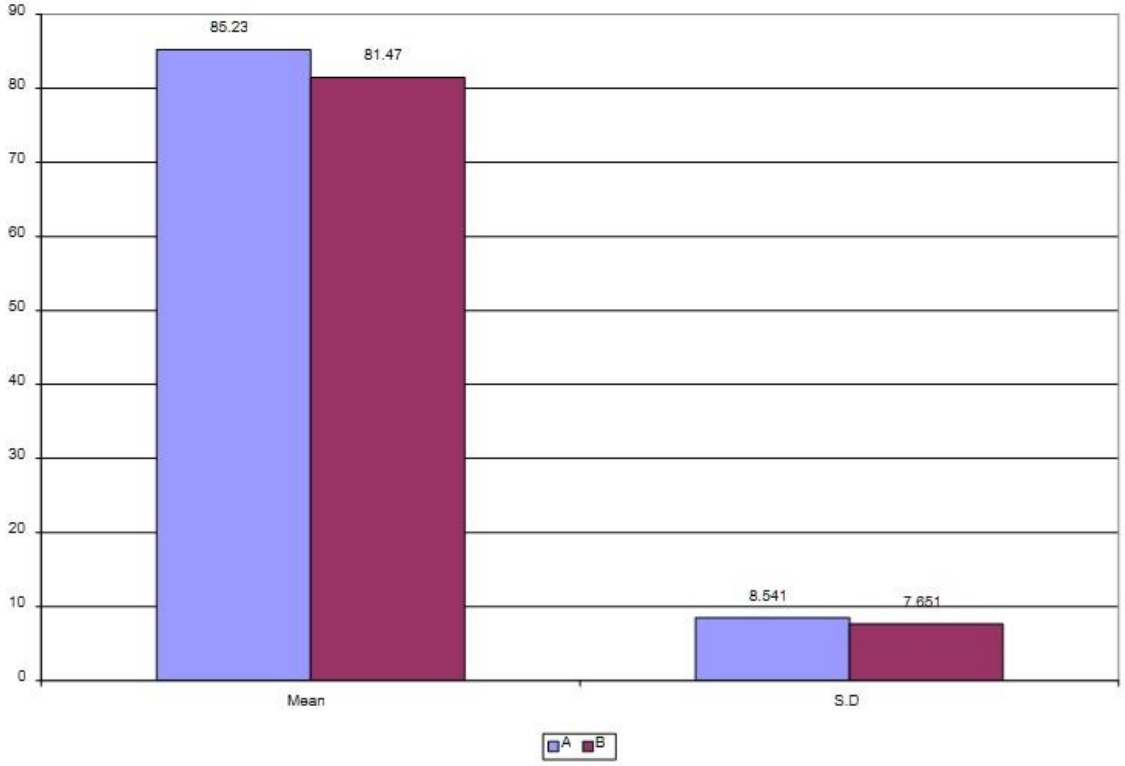
HEART RATE DATA DISTRIBUTION:

Table 11:

T-Test

Baseline HR	n	Mean	S.D	T	Df	Statistical inference
A	30	85.23	8.541	1.799	58	.077>0.05 Not Significant
B	30	81.47	7.651			

Diagram



The data regarding baseline and post-intubation heart rate were analyzed using t test

The mean base line heart rate of

Group A was 85.23 with an SD of 8.541

Group B was 81.47 with an SD of 7.651

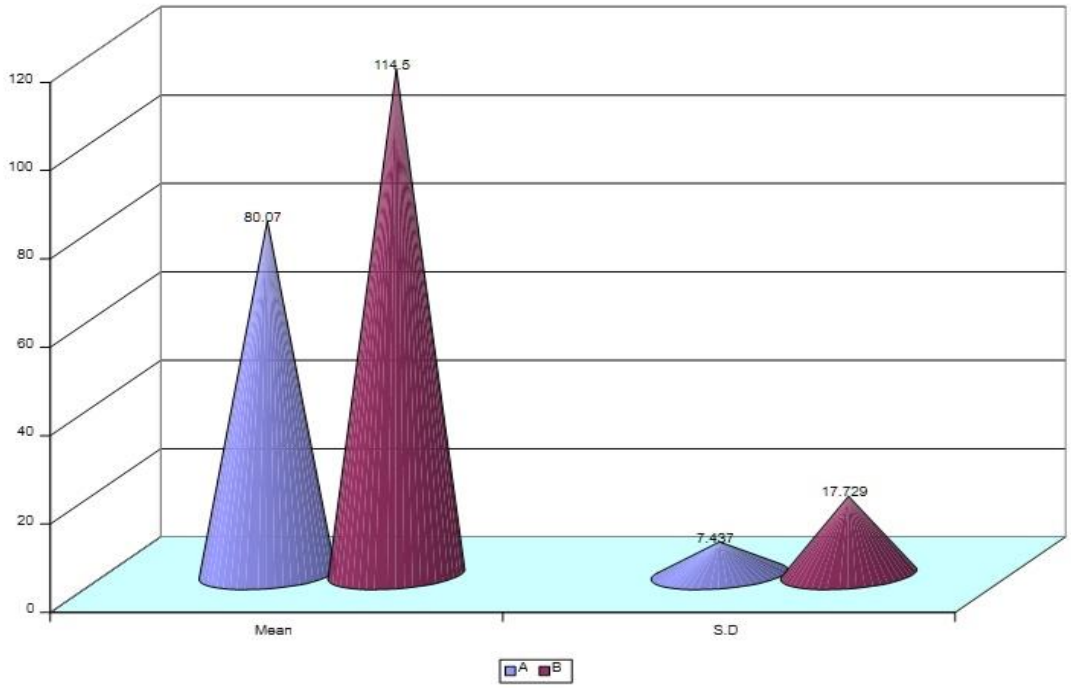
The P value of baseline heart rate correlation for both groups was 0.77 which is greater than 0.05 and hence statistically not significant.

Table 12:

T-Test

Post intubation HR	n	Mean	S.D	T	Df	Statistical inference
A	30	80.07	7.437	9.810	58	.000<0.05 Significant
B	30	114.50	17.729			

Diagram



The mean post intubation heart rate for group A was 80.07 with an SD of 7.437

The mean post intubation heart rate for group B was 114.50 with an SD of 17.729

The P value is 0.000 which is less than 0.05 and is statistically significant

The difference between the mean of baseline heart rate and post intubation heart rate in group A was a reduction by 5.1.

Group B was a increase by 33.03

Thus the variation in heart rate is minimal for group A than group B

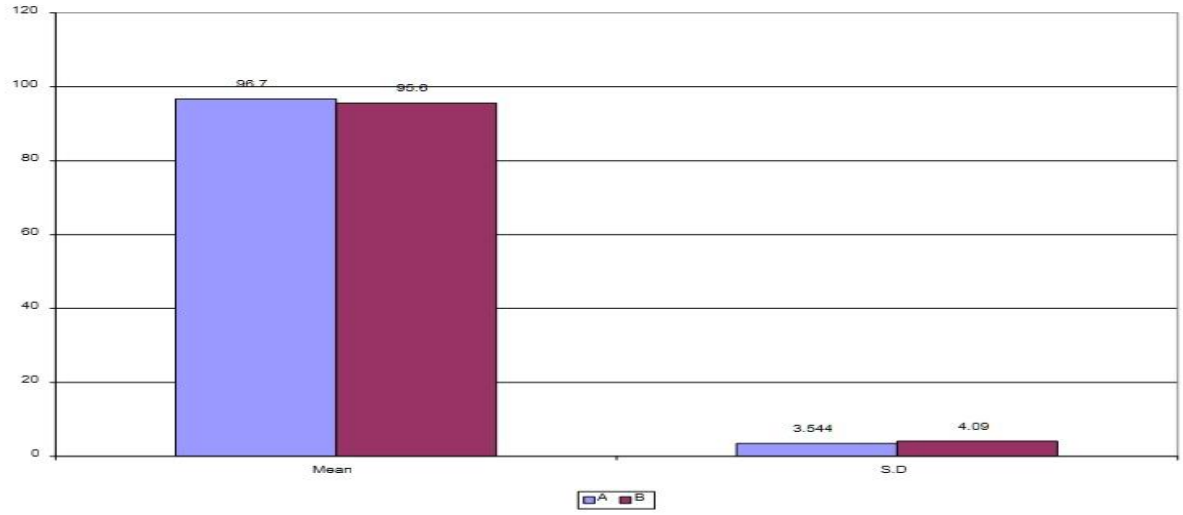
MEAN ARTERIAL PRESSURE DATA DISTRIBUTION:

Table 13:

T-Test

Base line Map	n	Mean	S.D	T	Df	Statistical inference
A	30	96.70	3.544	1.113	58	.270>0.05 Not Significant
B	30	95.60	4.090			

Diagram



The data regarding mean arterial pressure at baseline and post intubation for both groups were analyzed using t-test

The mean baseline MAP of

Group A was 96.70 mm Hg with an SD of 3.544 mmHg

Group B was 95.60 mm Hg with an SD of 4.090 mm Hg

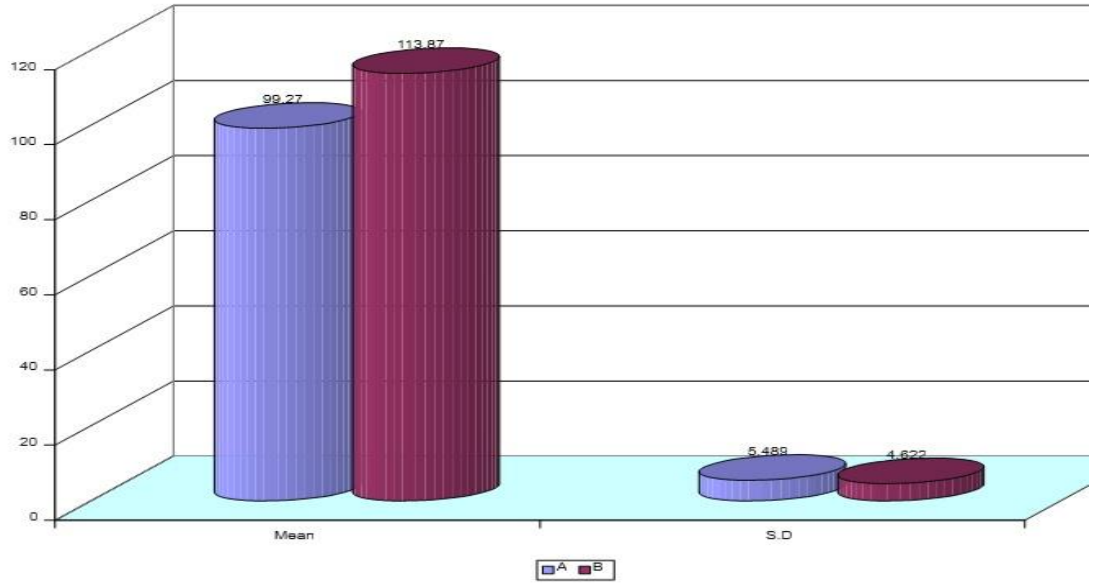
The P value for baseline MAP correlation for both groups was 0.270 which is greater than 0.05 and hence statistically not significant

Table 14:

T-Test

Post Intubation Map	n	Mean	S.D	T	Df	Statistical inference
A	30	99.27	5.489	11.144	58	.000<0.05 Significant
B	30	113.87	4.622			

Diagram



The mean post intubation MAP for ,

Group A was 99.27 with an SD of 5.489

Group B was 113.87 with an SD OF 4.622

The P value for the post intubation MAP correlation for both groups was 0.000 which is less than 0.05 which is statistically significant.

The difference between the mean of baseline MAP and post intubation MAP in

Group A was an increase by 2.57 mm Hg

Group B was an increase by 18.27 mm Hg

Thus the variation in mean arterial pressure is minimal for group A than group B.

DISCUSSION

The thrust to move away from Invasive techniques (Tracheotomy/ Tracheostomy) to Non invasive techniques has given rise to an array of techniques like Laryngoscopy, Orotracheal Intubation and more recently Fibre Optic Intubation in Modern anaesthetic care. The arrival of Laryngoscope blades and the subsequent orotracheal intubation has been the Mainstay of Non invasive airway Management since the last century.

However, Orotracheal intubation using Laryngoscopy in an Anesthetized patient could not be performed in all patients especially in patients with difficult airway and it posed a variety of difficulties which are as follows:

i. Loss of Muscle tone and the subsequent collapse of soft tissues of the airway leading to airway obstruction.
ii. Desaturation events are high in an anesthetized patients and difficult to intubate scenarios

The recent use of Fiberoptic bronchoscope for intubation in an awake state under conscious sedation can overcome the previously enlisted difficulties. The awake state of the patients enables the preserved muscle tone of the soft tissues of the airway maintaining its patency, less desaturation events, spontaneous breathing opens up airway leading to

easier intubation. Further, in those with difficult airways, FOB intubation could be successfully performed.

The history of Fiberoptic intubation can be traced to the last few decades of the 20th century. In 1967, a choledocoscope was first used to intubate a patient with still's disease (35). The use of Fiberoptic intubation then was mainly for diagnostic purpose of airway conditions and in recent times, Fiberoptic bronchoscopy intubation has become the First choice of intubation in difficult airway cases.

Endotracheal intubation in an awake state, if performed without adequate sedation can be an unpleasant and discomforting experience for the patient. The various drugs used for sedation during AFOI are as follows:-

i. Benzodiazepine (Midazolam)
ii. Propofol
iii. Alpha 2 agonists (clonidine &Remifentanyl)
iv. Ketamine

The above mentioned drugs can be used alone or in combination with others and in various dosages as per the requirements of the patient, clinical settings, operative conditions. An ideal sedative regimen for AFOI should provide,

i. Patient comfort & co operation

ii. Amnesia

iii. Anxiolysis

iv. Anti tussive properties / Attenuation of airway Reflexes

v. Stable hemodynamics

vi. Maintenance of a patent airway

The search for an Ideal sedative regimen for Awake Fibre optic Intubation is being constantly pursued by various clinical studies. This study aims to compare the efficacy and efficiency of Dexmedetomidine and Fentanyl for sedation for AFOI.

Dexmedetomidine is a highly selective alpha 2 agonist mainly acting upon the pontine Locus coeruleus nucleus producing sedation. Further, it has Anxiolytic, Analgesic and Anti sialogogue properties. An important property of Dexmedetomidine is that it produces sedation without respiratory depression; in contrast opioid agonists produce respiratory depression along with sedation.

Fentanyl is a highly selective opioid u receptor agonist producing sedation, analgesia. It has Antitussive properties. At a dose of 1 to 2 ug/kg, it decreases respiratory rate and increases tidal volume. At a dose of 3 ug/kg or above, Fentanyl decreases both the respiratory rate and tidal volume, further, it attenuates the ventilatory drive.

STUDY DESIGN:

In the context of the above, we have undertaken a study to compare the efficacy and efficiency of Dexmedetomidine (1 ug/kg over 10 min) and Fentanyl (2 ug/kg over 10 min) for sedation for Awake Fiberoptic intubation.

A total of 60 patients with ASA – PS I & II with Mallampati grading I & II posted for elective surgery undergoing general anaesthesia in Government Theni Medical college, Theni were selected for the study. A well informed written consent was obtained from all of them.

The patients were randomly allotted into two groups with 30 patients each.

i. Group A (n = 30) – received study drug Inj. Dexmedetomidine (1 ug/kg over 10 min)
ii. Group B (n = 30) = received study drug Inj. Fentanyl (1 ug/kg over 10 min)

All patients had been counselled about the procedure and were premedicated with drugs T. Alprazolam 0.5 mg the night before the surgery, T.Ranitidine 150 mg and T. Ondansetron 4 mg were given 2 hours before the surgery. Inj. Glycopyrrolate 0.2 mg IV. Topical anaesthesia of the airway was achieved with Nebulisation of 2% lidocaine

4 ml over 20 minutes. Then as per the patients grouping, study drug Inj. Dexmedetomidine Infusion at a dose of 1ug/kg over 10 min was given to Group A and Inj. Fentanyl at a dose of 2ug/kg over 10 min was given to Group B. The nostrils were prepared with xylometazoline drops and lidocaine jelly. At the end of study drug Infusion, the level of sedation was assessed using the Ramsay sedation score. An RSS >=2 was considered appropriate before Intubation. If the sedation of RSS >=2 could not be achieved, Inj. Midazolam as a rescue sedation was used. A well lubricated Fiberoptic bronchoscope preloaded with the appropriate ETT was inserted through the Nasal route and Intubation was successfully performed in all the patients.

Intubation condition was assessed by COUGH SCORE during bronchoscopy. Tolerance to intubation was assessed by the POST NTUBATION SCORE. The Mean Arterial Pressure and the Heart Rate of the patient was recorded at the Baseline before the intubation and after the intubation. Oxygen saturation using SpO_2 was monitored throughout the Intubation procedure and the lowest reading was noted.

All the recordings were tabulated and statistical analysis was done.

INTERPRETATION OF RESULTS

1. Age, Sex, Weight, ASA – PS correlation:

Both the Groups A & B are comparable in terms of the patients Demographic characteristics like Age (P value 0.725 > 0.05), sex (p value 1.000 > 0.05), weight (P value 0.623 > 0.05), ASA - PS (P value 0.718 > 0.05) and no statistical significance between the two groups exist in terms of the above mentioned criteria.

2. Cough Score correlation:

A cough score of less than or equal to 2 was considered as a favourable intubation condition. In this study, cough score <= 2 was achieved in 27 patients out of 30 patients in Group A whereas in only 3 out of 30 patients in Group B. The difference is statistically significant (P value 0.001 < 0.005). Thus cough score was significantly favourable in Group A than Group B.

3. Post Intubation Score correlation:

The best post intubation score of 1 (co operative) was achieved in 27 out of 30 patients in Group A whereas in only 3 out of 30 patients in Group B. The difference is statistically significant (P value 0.002 < 0.05). Thus, the post intubation score is significantly favourable for Group A than Group B.

Chu et al had observed better tolerance of endotracheal intubation without upper airway obstruction and respiratory depression in the Dexmedetomidine group (1ug/kg) compared with the Fentanyl group (1ug/kg)[36].

Bergere et al has observed that Dexmeditomidine in combination with low dose Midazolam is more effective than Midazolam alone for sedation in Awake Fiberoptic Intubation and that Dexmedetomidine at 1ug/kg bolus was safe and beneficial for patients undergoing Awake Fiberoptic intubation even without airway nerve block or topical Anaesthesia [37].

Further, Dexmedetomidine has been proved as an effective sedative agent for AFOI in difficult airway scenarios [38]

4. Ramsay sedation score correlation:

A Ramsay sedation score of >=2 was considered appropriate for intubation. In our study, 80% of patients in Group A (24 out of 30 patients) could achieve a higher RSS Score of 3 where as 83.3% of patients in Group B (25 out of 30 patients) achieved the Lower RSS 2. The difference is statistically significant (P value 0.004 < 0.05). Thus Ramsay sedation score is significantly favourable for Group A than Group B. Further, in 2 patients in Group B, the Ramsay sedation score was 1 (Anxious, Agitated or Restless), so Inj. Midazolam was used as a Rescue sedation.

5. Oxygen saturation, Heart Rate, Mean Arterial Pressure correlation:

The mean SpO_2 in Group A was 96.60% with an SD of 1.653% whereas in Group B, it was 93.10% with an SD of 2.107%. The difference is statistically significant (P value 0.000 < 0.05). Thus, desaturation events are significantly less in Group A than Group B. The Desaturation events are managed by administering oxygen through the bronchoscope port.

The mean Base line Heart Rate in Group A was 85.23 with an SD of 8.541 and in Group B was 81.47 with an SD of 7.651.

The mean Post intubation Heart Rate in Group A was 80.07 with an SD of 7.437 and in Group B was 114.50 with an SD of 17.729.

Thus there was significant change in the Heart Rate in Group B between baseline and post intubation recordings while in Group A, there was no significant changes. The difference is statistically significant (P value 0.000 < 0.05).

There was no incidence of bradycardia in any of the patients in both the groups. However, it has to be noted that in Group A, the mean Baseline HR reduced by 5.16 in the post intubation recording. This can be attributed to Dexmedetomidine causing decreased Nor adrenaline release, decreased centrally mediated sympathetic tone and increased vagal activity.

Peden et al observed bradycardia and sinus arrest in young volunteers following Dexmeditomidine bolus and infusion[39]. Since, in this study, Inj. Glycopyrrolate was administered as an anti sialogogue, the reduction response of Heart Rate to Dexmeditomidine may have been attenuated to a significant extent.

The Mean Baseline MAP for Group A was 96.70 mmHg with an SD of 3.544 mmHg and in Group B was 95.60 mmHg with an SD of 4.090 mmHg.

The Mean Post intubation MAP for Group A was 99.27 with an SD of 5.489 and in Group B was 113.87 with an SD of 4.622.

Thus, it can be seen that there is significant changes in MAP between baseline and post intubation recordings in Group B whereas no significant change was observed in Group A. The difference is statistically significant ($0.000 < 0.05$).

Venn et al reported unaltered hemodynamics even in higher doses of Dexmedetomidine Infusion[40].

To summarize, Dexmedetomidine is more effective than Fentanyl during Awake Fiberoptic intubation, as it provides better sedation, patient comfort, better intubation condition, Hemodynamic stability and less desaturation.

SUMMARY

We conducted a comparative study of Inj. Dexmedetomidine (1ug/kg over 10 min) and Inj. Fentanyl (2ug/kg over 10 min) for better sedation and patient comfort in those undergoing elective Awake Fiberoptic Intubation. A total of 60 patients were selected for the study and they were randomly categorized into Group A and Group B. All patients are premedicated with T. Ranitidine 150mg and T. Ondansetron 4mg 2 hours before surgery and all received Inj. Glycopyrrolate 0.2mg as Anti Sialogogue. Group A received study drug Inj. Dexmedetomidine at a dose of 1ug/kg over 10 min and Group B received Inj. Fentanyl at a dose of 2 ug/kg over 10 min. The level of sedation was evaluated using Ramsay sedation score and the Intubation condition were evaluated using cough score during bronchoscopy. Tolerance to intubation was evaluated by the Post intubation score after successful placement of endotracheal tube in the trachea. Further, oxygen saturation was continuously monitored using $SPO_{2.}$ Other Hemodynamic parameters like HR, MAP were recorded at the baseline prior to the procedure and post intubation.

In analysis, we have observed that both Group A and Group B has comparable demographic characteristics (Age, sex, weight). Further, Ramsay sedation score, cough score, post intubation score were significantly favourable in Group A than in Group B. Significantly less

desaturation were observed in Group A than Group B. Hemodynamic parameters like Heart Rate and Mean Arterial pressure did not show significant variability between baseline and post intubation values in Group A when compared with that of Group B.

CONCLUSION

In our study, we have shown that Inj. Dexmedetomidine (1ug/kg over 10 min) is more effective than Inj. Fentanyl (2ug/kg over 10 min) for Awake Fiberoptic Intubation in terms of better sedation, intubating conditions and tolerance to intubation.

- Inj. Dexmedetomidine produces minimal or No respiratory depression when compared with that of Inj. Fentanyl resulting in less desaturation events than the latter.
- Hemodynamic changes (HR, MAP) are insignificant with Inj. Dexmedetomidine when compared with that of Inj. Fentanyl.

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PROFORMA

GOVT THENI MEDICAL COLLEGE AND HOSPITALS

DEPT OF ANAESTHESIOLOGY

COMPARISON B/W FENTANYL AND DEXMEDITOMIDINE FOR AWAKE FIBROPTIC INTUBATION

NAME: AGE/SEX: IP NO:

DIAGNOSIS:

PROCEDURE DONE:

ASA RISK:

PREMEDICATION: Inj ranitidine / inj ondnsetrone / inj glycol

MPG:

AIRWAY ASESSMENT:

PATENCY OF BOTH NOSTRILS:

LIGNOCAINE [4% ML] NEBULISATION:

PULSE:

BP:

SPO2:

FENTANYL/DEXMEDITOMIDINE:

RAMSAY SEDATION SCORE: 1/2/3/4/5/6

LIGNOCAINE 10% SPRAY:

ETT:

COUGH SCORE: [INTUBATING CONDITION] – 1/2/3/4

POST INTUBATION SCORE: 1/2/3

PULSE:

BP:

SPO2:

COMPLICATIONS IF ANY AND MANAGEMENT:

MASTER CHART

GROUP – A DEXMEDETOMIDINE

S.NO	AGE	WEIGHT	ASA-PS	COUGH SCORE	POST INTUBATION SCORE	RAMSAY SEDATION SCORE	SPO2	BASELINE HR	POST INTUBATION HR	BASE LINE MAP	POST INTUBATION MAP
1.	33/M	64	I	2	1	3	97%	100	90	99	97
2.	37/M	70	I	2	2	3	98%	90	85	102	106
3.	32/M	65	I	2	1	3	98%	98	75	93	87
4.	41/M	52	II	1	1	3	97%	78	65	96	86
5.	49/F	58	I	2	1	2	96%	98	90	101	100
6.	25/M	60	I	2	1	3	94%	90	86	97	93
7.	31/M	58	I	3	1	2	97%	94	90	98	103
8.	30/F	54	I	2	1	3	97%	83	86	93	107
9.	47/M	66	II	2	1	2	97%	74	70	94	98
10.	36/F	64	I	2	1	3	98%	83	79	95	101
11.	24/M	71	I	2	1	4	92%	95	89	100	106
12.	46/M	63	I	2	1	3	99%	88	82	103	101
13.	27/M	55	I	2	1	3	96%	74	71	96	101
14.	33/F	66	I	3	1	3	97%	78	70	93	97
15.	28/M	57	I	2	1	3	99%	93	90	95	104

16.	37/F	67	I	2	1	3	96%	81	76	97	99
17.	44/M	69	I	1	2	3	95%	88	82	91	96
18.	25/F	56	I	2	1	3	98%	102	91	90	93
19.	31/M	65	II	2	1	3	96%	88	83	99	104
20.	26/M	62	I	2	1	3	97%	79	80	96	101
21.	35/F	73	I	2	1	2	97%	84	80	100	102
22.	48/F	63	I	2	1	3	93%	74	78	94	96
23.	36/F	77	I	2	1	3	96%	86	81	96	92
24.	24/F	68	I	2	1	3	98%	91	88	94	97
25.	46/M	71	II	3	1	3	95%	78	71	98	99
26.	23/F	66	I	2	1	3	96%	83	79	97	104
27.	26/M	58	I	2	2	3	99%	74	70	95	98
28.	28/F	62	I	2	1	4	96%	81	78	95	98
29.	43/F	63	II	2	1	3	98%	72	74	106	110
30.	39/M	74	I	2	1	3	96%	80	73	98	102

GROUP – B FENTANYL

S.NO	AGE	WEIGHT	ASA-PS	COUGH SCORE	POST INTUBATION SCORE	RAMSAY SEDATION SCORE	SpO2	BASELINE HR	POST INTUBATION HR	BASELINE MAP	POST INTUBATION MAP
1.	47/M	66	II	3	2	2	93%	68	101	97	116
2.	28/F	52	I	3	2	1	91%	80	100	88	108
3.	25/F	55	I	3	2	2	97%	90	114	93	110
4.	30/M	70	I	3	3	2	94%	102	112	97	112
5.	22/M	58	I	3	2	3	90%	79	89	89	105
6.	21/M	65	I	3	2	2	92%	72	108	94	106
7.	39/M	74	I	2	2	2	94%	91	107	89	109
8.	24/F	58	I	3	2	2	96%	79	101	103	118
9.	38/M	66	II	3	1	2	89%	78	118	98	115
10.	26/F	58	I	3	2	2	93%	84	112	97	113
11.	33/M	62	I	3	2	2	92%	91	122	104	115
12.	25/M	73	I	3	2	2	94%	83	117	94	110
13.	34/M	68	I	3	2	3	91%	77	109	96	116
14.	42/F	55	I	3	2	2	93%	73	106	93	111
15.	38/M	65	I	3	2	2	96%	81	116	97	116
16.	23/F	69	I	3	2	2	94%	90	122	91	110
17.	37/M	58	I	3	2	2	93%	70	104	94	116
18.	47/M	63	II	2	2	2	94%	79	111	99	120

19.	38/F	69	I	3	1	1	91%	88	124	101	123
20.	31/M	78	I	3	2	2	90%	75	198	89	109
21.	26/F	58	I	3	2	2	94%	84	120	94	117
22.	33/F	64	I	3	2	2	98%	80	117	95	112
23.	43/M	69	I	3	2	2	90%	76	118	97	113
24.	28/M	63	I	3	3	2	92%	93	117	93	118
25.	42/F	74	I	3	2	2	93%	73	108	102	119
26.	29/F	67	I	3	3	2	94%	81	126	96	115
27.	36/M	64	I	3	2	3	93%	76	109	98	116
28.	47/F	63	I	3	2	2	94%	79	107	94	118
29.	33/M	66	I	2	1	2	93%	88	114	97	122
30.	43/F	71	II	3	2	2	95%	84	108	99	108

Ref. No. 2643/ME1/17

Government Theni Medical College
Theni Dated: 28.04.2017

Institutional Ethical Committee:

Convenor:

Dr. T. Thirunavukkarasu, M.D., D.A.,
Dean
Govt. Theni Medical College
Theni

Sub: Medical Education – Govt. Theni Medical College,
Theni – Ethical Committee – Minutes – Communicated – Reg.

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The Ethical Committee Meeting of the Govt. Theni Medical College, Theni was held at 11.00 A.M. on 28.04.2017 at Conference Hall, Near Dean's Chamber, Government Theni Medical College, Theni.

The following Members of the Committee have attended the Meeting.

1.	**Convener**	:	**Dr. T. Thirunavukkarasu, M.D., D.A., Dean**
2.	**Member Secretary**	:	**Dr. M. Ilangovan, M.S., Deputy Superintendent**
3.	**Members**		
	Professor of Medicine	:	**Dr. P. Purushothaman, M.D.,**
	Professor of Surgery	:	**Dr. R. Murugesan, M.S.,**
	Professor of Obs. & Gynaec.	:	**Dr. Thangamani, M.D., O.G.,**
	Professor of Micro Biology	:	**Dr. K.M. Mythreyee, M.D.,**
4.	**Chairman (Private Consultant)**	:	**Dr. Paulraj, M.D.,** Ramya Clinic, Periyakulam Road, Theni.
5.	**Lawyer**	:	**Thiru.K.Murugesan, B.Com., B.L.,** S/o.Kamaraj, Ambedkar Nagar, Varusanadu, Theni District.
6.	**Sociologist**	:	**Sr. Anaestescia** Director, Jeevan Jothi Hospital Community Care Centre, Periyakulam Road, Kailasapatti, Theni Dist.
7.	**Public**	:	**Mr. P. Deenadhayalan, M.A.,** Land Lord, Koduvilarpatti, Theni District.

The following Project was approved by the Committee:

Name and Designation	Name of the Project	Remarks
Dr. S. Mahaminu I Year MD (Anaes.) Post Graduate	Comparison between pentanyl and dexmedetomidine for awake fiberoptic intubation	Approved

Please note that the investigator should adhere the following: He/she should get a detailed informed consent from the Patients/participants and maintain Confidentially.

1. He/she should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution.
2. He/she should inform the Institution Ethical Committee in case of any change of study procedure site and investigation or guide.
3. He/she should not deviate for the area of the work for which applied for Ethical Clearance. He/She should inform the Institution Ethical Committee immediately, in case of any adverse events or any serious adverse reactions.
4. He/she should abide to the rules and regulations of the institution.
5. He/she should complete the work within the specific period and apply for if any extension of time is required. He/she should apply for permission again and do the work.
6. He/she should submit the summary of the research work to the Ethical Committee on completion of the work.
7. He/she should not claim any funds from the institution while doing the work or on completion.
8. He/she should understand that the members of Institutional Ethical Committee have the right to monitor the work with prior intimation.

Convenor

To

The above individual – through Head of the Department concerned.

URKUND

Urkund Analysis Result

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http://ispub.com/IJA/12/2/10785
http://file.scirp.org/Html/4-1920484_81509.htm
https://en.wikipedia.org/wiki/Fiberoptic_intubation
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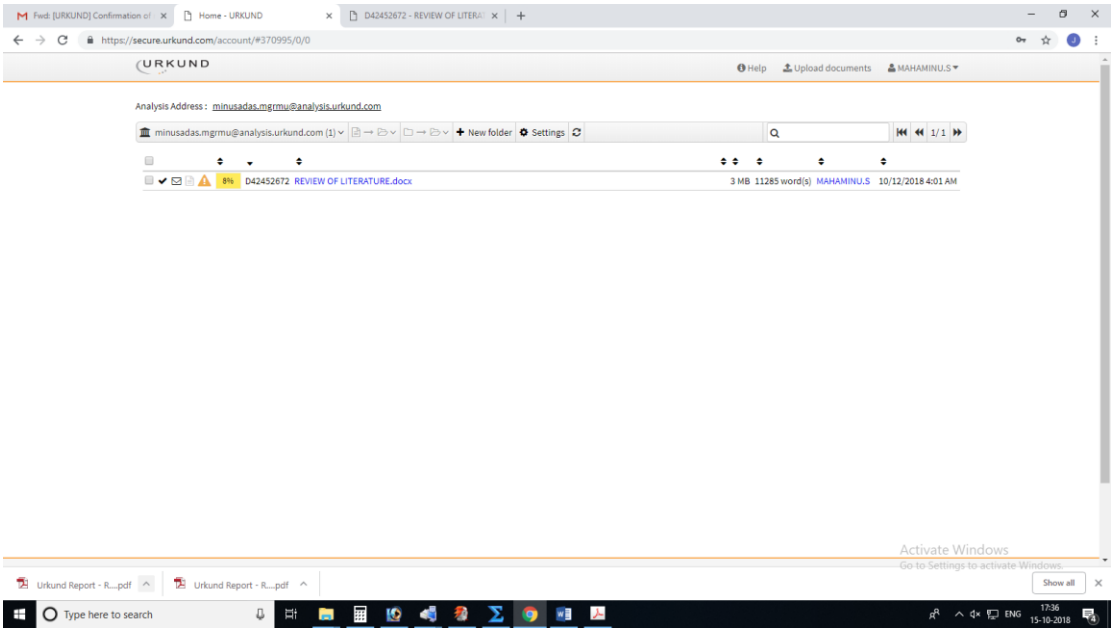
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CERTIFICATE – II

This is to certify that this dissertation work titled "**EXTRAFASCIAL INJECTION FOR INTERSCALENE BRACHIAL PLEXUS BLOCK REDUCES RESPIRATORY COMPLICATIONS COMPARED WITH A CONVENTIONAL INTRAFASCIAL INJECTION**" of the candidate **Dr.S.SOWMIYA** with **Registration Number: 201620106** for the award of Master Degree in the branch of **ANAESTHESIOLOGY**. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **2** percentage of plagiarism in the dissertation.

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